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1 (Pages 1 to 4)

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1	PROCEEDINGS	1	(Exhibit 237 was marked for
2	(Witness sworn.)	2	identification.)
3	DR. ANDREA KURZ	3	BY MR. ASSAAD:
4	called as a witness, being first duly sworn,	4	Q. Exhibit 237 is a copy of your curriculum
5	was examined and testified as follows:	5	vitae that I I received through discovery from your
6	ADVERSE EXAMINATION	6	office in the past few months. Is this a current copy
7	BY MR. ASSAAD:	7	of your curriculum vitae?
8	Q. Good morning, Dr. Kurz. My name's Gabriel	8	A. One second.
9	Assaad and I represent the plaintiffs in a multi-	9	Almost, yes.
10	district litigation that's being held in Minnesota.	10	Q. "Almost." When you say "almost," what's
11	Let us begin by if you could just state your	11	missing?
12	full name for the record.	12	A. A few publications.
13	A. Andrea Kurz.	13	Q. Any currently ongoing research that is
14	Q. And what is your current business address?	14	missing from this curriculum vitae?
15	A. Actually this building, so it is 1500 Euclid	15	A. Yes.
16	Avenue, Cleveland. And I'm always getting mixed up if	16	Q. What's missing?
17	it's 43193, I think.	17	A. Oh, there are I
18	Q. That's fine. We don't that's that's	18	I can't tell you exactly. I know that I
19	close enough.	19	have over 200 papers by now, so which ones exactly the
20	Have you ever had your deposition taken	20	ones are that are missing, I don't know.
21	before?	21	Q. Well let me let me see if
22	A. No.	22	The last page is "CURRENTLY ONGOING
23	Q. Okay. I'm going to go through a few	23	RESEARCH."
24	ground ground rules, and first and foremost, let's	24	A. Oh, the current. Yeah.
25	try to wait for each each person to finish their	25	Q. Is there any currently ongoing research
1	question and answer before the other one speaks so we	1	that's not on this list that you're doing for 3M at
2	have a clear record for the court reporter. Do you	2	this at this moment?
3	understand?	. 3	A. There might be a retrospective study about
4	A. I do.	4	predictors of hypothermia which is not on there yet,
5	Q. Okay. Second, please, when you answer,	5	and then there is one study with 3M which we'll be
6	answer verbally. "Mm-hmm" or "uh-huh" doesn't really	6	doing in China that hasn't started yet and so that is
7	get written down well by the court reporter; it's much	7	not on there yet.
8	easier for him just to have a verbal answer. Do you	8	Q. Is that the Protect?
9	understand?	9	A. Yes, that's the Protect trial. Exactly.
10	A. Uh-huh. Yes.	10	Q. Any study that you're doing with 3M that
11 .	Q. Finally, I'm going to ask you numerous	11	deals with hypothermia and infection rates?
12	questions today. If you don't understand my question,	12	A. The Protect.
13	please let me know. Fair enough?	13	Q. Okay. So doctor, can you just briefly
14	A. Yes. Sure.	14	describe your background, starting off or your
15	Q. If you answer my question, I will assume	15	educational background, going with college to medical
16	that you understood the question. Fair?	16	school, residency.
17	A. Yes.	17	A. So I went
18	Q. Any time you want to take a break, that is	18	I grew up in Vienna, Austria, so I actually
19	fine, but please request a break after a question and	19	didn't go to college because we don't have that there.
20	answer has been has been completed. Fair enough?	20	After high school or gymnasium I did medical school in
21	A. Yes.	21	Vienna, thereafter did a research fellowship in
22	MR. ASSAAD: I'd like to mark as Exhibit	22	actually, after med school I started residency in
		23	Vienna. In the fourth or fifth year of residency,
23	No		•
	THE REPORTER: 237. MR. ASSAAD: 237	24 25	started a research fellowship at the University of San Francisco of California in San Francisco.

	Page 9		Page 11
1	Q. And what year was that, the research	1	with your work at Outcomes Research?
2	fellowship?	2.	A. My clinical practice is 50 percent, the rest
3	You can look at your CV.	3	is administration, and part of that is research, and
4	A. I think it started	4	that's when I when we collaborate with Outcomes
5	I should know that. It started from '93 to	5	Research.
6	196.	6	Q. And
7	Q. Okay.	7	A. So I can't give you a percentage exactly.
8	A. Then I	8	Q. That's fine.
9	Q. You were actually in San Francisco at that	9	And and going back to the instructions,
10	time?	10	I I don't want you to guess, I don't want you to
11	A. Yes.	11	speculate. If you don't know the answer, it's
12	Q. Okay. I just I don't mean to interrupt.	12	perfectly fine
13	I'll try not to do that in the future. But according	13	A. Uh-huh.
14	to your CV, it says your education, University of	14	Q to say "I don't know." Fair enough?
15	Vienna, 1990 to 1994.	15	A. Yes.
16	A. Yeah.	16	Q. All right. With respect to your clinical
17	Q. So your	17	practice, can you describe your clinical practice?
18	A. That overlaps.	18	A. I work in the operating rooms and
19	Q. Overlaps. Okay.	19	anesthetize patients 50 percent of my time. When I do
20	Continue.	20	that I usually either supervise residents or nurse
21	A. So thereafter I went back to Vienna, got my	21	anesthetists. And that's pretty much it, I think.
22	professorship there. Then	22	Q. Are you in a certain do you
23	Q. And what year was that?	23	Do you handle more than like one type of
24	A. 196.	24	surgery or the other?
25	Then in '98 or '99 I have to look it up	25	A. Mainly urology, but otherwise everything.
***************************************	Page 10		Page 12
1	almost I went to Washington University in St. Louis	1	Q. When you okay. When you say "mainly
2	as Director of the Division of Clinical Research	2.	urology," what percentage of your of your clinical
3	there. Thereafter, was recruited in 2004 or '3 as the	3	practice is anesthizing anes anesthesia
4	chair of the Department of Anesthesia at the	i .	
	chair of the Department of Altesthesia at the	4	patients dealing with anesthesia patients in
5	University of Bern in Switzerland and now I don't	4 5	patients dealing with anesthesia patients in urology?
5 6	•	1	urology?
	University of Bern in Switzerland and now I don't	5	
6	University of Bern in Switzerland and now I don't know when it was exactly, but I think it was '3, end	5 6	urology? A. Approximately 60 percent.
6 7	University of Bern in Switzerland and now I don't know when it was exactly, but I think it was '3, end of '3, beginning of '4 and in 2007 left Switzerland	5 6 7	urology? A. Approximately 60 percent. Q. Do you handle any anesthesia services for
6 7 8	University of Bern in Switzerland and now I don't know when it was exactly, but I think it was '3, end of '3, beginning of '4 and in 2007 left Switzerland and joined the Department of Outcomes Research here at	5 6 7 8	urology? A. Approximately 60 percent. Q. Do you handle any anesthesia services for orthopedic patients? A. I work there, yes.
6 7 8 .9	University of Bern in Switzerland and now I don't know when it was exactly, but I think it was '3, end of '3, beginning of '4 and in 2007 left Switzerland and joined the Department of Outcomes Research here at the Cleveland Clinic.	5 6 7 8 9	urology? A. Approximately 60 percent. Q. Do you handle any anesthesia services for orthopedic patients? A. I work there, yes. Q. So you
6 7 8 .9	University of Bern in Switzerland and now I don't know when it was exactly, but I think it was '3, end of '3, beginning of '4 and in 2007 left Switzerland and joined the Department of Outcomes Research here at the Cleveland Clinic. Q. So since 2007 you've been here at the	5 6 7 8 9	urology? A. Approximately 60 percent. Q. Do you handle any anesthesia services for orthopedic patients? A. I work there, yes.
6 7 8 .9 10	University of Bern in Switzerland and now I don't know when it was exactly, but I think it was '3, end of '3, beginning of '4 and in 2007 left Switzerland and joined the Department of Outcomes Research here at the Cleveland Clinic. Q. So since 2007 you've been here at the Cleveland Clinic?	5 6 7 8 9 10 11	urology? A. Approximately 60 percent. Q. Do you handle any anesthesia services for orthopedic patients? A. I work there, yes. Q. So you A. Very little.
6 7 8 .9 10 11	University of Bern in Switzerland and now I don't know when it was exactly, but I think it was '3, end of '3, beginning of '4 and in 2007 left Switzerland and joined the Department of Outcomes Research here at the Cleveland Clinic. Q. So since 2007 you've been here at the Cleveland Clinic? A. Yes. And I was vice chair of the Department	5 6 7 8 9 10 11	urology? A. Approximately 60 percent. Q. Do you handle any anesthesia services for orthopedic patients? A. I work there, yes. Q. So you A. Very little. Q. Okay. And I'm
6 7 8 .9 10 11 12	University of Bern in Switzerland and now I don't know when it was exactly, but I think it was '3, end of '3, beginning of '4 and in 2007 left Switzerland and joined the Department of Outcomes Research here at the Cleveland Clinic. Q. So since 2007 you've been here at the Cleveland Clinic? A. Yes. And I was vice chair of the Department of Outcomes Research, and in 2014 I became chair of	5 6 7 8 9 10 11 12 13	urology? A. Approximately 60 percent. Q. Do you handle any anesthesia services for orthopedic patients? A. I work there, yes. Q. So you A. Very little. Q. Okay. And I'm Now would that include total hip and total
6 7 8 9 10 11 12 13	University of Bern in Switzerland and now I don't know when it was exactly, but I think it was '3, end of '3, beginning of '4 and in 2007 left Switzerland and joined the Department of Outcomes Research here at the Cleveland Clinic. Q. So since 2007 you've been here at the Cleveland Clinic? A. Yes. And I was vice chair of the Department of Outcomes Research, and in 2014 I became chair of the Department of General Anesthesiology within the	5 6 7 8 9 10 11 12 13	urology? A. Approximately 60 percent. Q. Do you handle any anesthesia services for orthopedic patients? A. I work there, yes. Q. So you A. Very little. Q. Okay. And I'm Now would that include total hip and total knee arthroplasty?
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	University of Bern in Switzerland and now I don't know when it was exactly, but I think it was '3, end of '3, beginning of '4 and in 2007 left Switzerland and joined the Department of Outcomes Research here at the Cleveland Clinic. Q. So since 2007 you've been here at the Cleveland Clinic? A. Yes. And I was vice chair of the Department of Outcomes Research, and in 2014 I became chair of the Department of General Anesthesia Institute here. Q. Okay. So 2014 you became chair of General Anesthesia A. General Anesthesia here. Q. That's not part of Outcomes Research; correct? A. It's not part of Outcomes Research, no.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	urology? A. Approximately 60 percent. Q. Do you handle any anesthesia services for orthopedic patients? A. I work there, yes. Q. So you A. Very little. Q. Okay. And I'm Now would that include total hip and total knee arthroplasty? A. Yes. Q. Do you use forced-air warming with all your patients? A. Yes. Q. And it's my understanding that Cleveland Clinic has gone from the Bair Hugger to the Mistral system.
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	University of Bern in Switzerland and now I don't know when it was exactly, but I think it was '3, end of '3, beginning of '4 and in 2007 left Switzerland and joined the Department of Outcomes Research here at the Cleveland Clinic. Q. So since 2007 you've been here at the Cleveland Clinic? A. Yes. And I was vice chair of the Department of Outcomes Research, and in 2014 I became chair of the Department of General Anesthesia Institute here. Q. Okay. So 2014 you became chair of General Anesthesia A. General Anesthesia here. Q. That's not part of Outcomes Research; correct? A. It's not part of Outcomes Research, no. Q. Do you have a clinical practice right now?	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	urology? A. Approximately 60 percent. Q. Do you handle any anesthesia services for orthopedic patients? A. I work there, yes. Q. So you A. Very little. Q. Okay. And I'm Now would that include total hip and total knee arthroplasty? A. Yes. Q. Do you use forced-air warming with all your patients? A. Yes. Q. And it's my understanding that Cleveland Clinic has gone from the Bair Hugger to the Mistral system. A. Yes.

3 (Pages 9 to 12)

	Page 13		Page 15
1	A. Two years ago.	1	Q. Was there any discussion as to the benefits
2	Q. Were you in the decision-making process to	2	of using the Mistral system, besides cost, compared to
3	change from the Bair Hugger warming unit to the	3	the Bair Hugger system?
4	Mistral?	4	A. No.
5	A. Yes.	5	Q. With respect to the change from the Bair
6	Q. Why did why did Cleveland Clinic change	6	Hugger system to the Mistral system, were you in favor
7	from the Bair Hugger warming unit to Mistral?	7	of the change, against the change, or indifferent?
8	A. Cost.	8	A. I was fairly indifferent.
9	Q. Is that the only reason?	. 9	Q. Did you provide any opinion with respect to
10	A. That was the only reason, yes.	10	whether or not Cleveland Clinic should change from the
11	Q. How much cheaper is the Mistral to use than	11	Bair Hugger warming system to the Mistral warming
12	the Bair Hugger?	12	system?
13	A. It's a few dollars. I cannot tell you what	13	A. No.
14	exactly it is.	14	Q. Was it when you did your fellowship in San
15	Q. A few dollars per blanket?	15	Francisco between 1993 and 1996 that you be that
16	A. Per blanket.	16	you met Dr. Sessler?
17	Q. Okay. Does does Mistral place the	17	A. Yes.
18	warming units like like 3M does?	18	Q. Did you know Dr. Sessler before that?
19	A. Yes.	19	A. Yes, I did.
20	Q. What role did you have in the decision-	20	Q. How?
21	making process?	21	A. Oh, through a through my research.
22	A. Only advisory.	22	Q. When you were at the University of Vienna?
23	Q. Are you on the advisory board for the	23	A. Of Vienna, yes.
24	37Company?	24	Q. And what was your research in at the
25	A. Currently, I don't know.	25	University of Vienna?
	Page 14		Page 16
1	Page 14 Q. At any point?	1	Page 16 A. We did the very first one of the first
1 2		1 2	
	Q. At any point?	l .	A. We did the very first one of the first
2	Q. At any point?A. I was, yes.	2	A. We did the very first one of the first Bair Hugger studies in Europe looking at whether one
2	Q. At any point?A. I was, yes.Q. Okay. And did any discussion during this	2 3	A. We did the very first one of the first Bair Hugger studies in Europe looking at whether one can keep patients normothermic with the Bair Hugger as opposed to not using anything, which was the standard of care at that point in time.
2 3 4	Q. At any point?A. I was, yes.Q. Okay. And did any discussion during this period of time in the decision making deal with the	2 3 4	A. We did the very first — one of the first Bair Hugger studies in Europe looking at whether one can keep patients normothermic with the Bair Hugger as opposed to not using anything, which was the standard of care at that point in time. Q. Okay. Well when you say "not using
2 3 4 5	 Q. At any point? A. I was, yes. Q. Okay. And did any discussion during this period of time in the decision making deal with the efficacy of the Mistral system as compared to the Bair Hugger system? A. Yes. 	2 3 4 5	A. We did the very first — one of the first Bair Hugger studies in Europe looking at whether one can keep patients normothermic with the Bair Hugger as opposed to not using anything, which was the standard of care at that point in time. Q. Okay. Well when you say "not using anything," you'd use blankets.
2 3 4 5 6	 Q. At any point? A. I was, yes. Q. Okay. And did any discussion during this period of time in the decision making deal with the efficacy of the Mistral system as compared to the Bair Hugger system? A. Yes. Q. And what was discussed? 	2 3 4 5 6	A. We did the very first — one of the first Bair Hugger studies in Europe looking at whether one can keep patients normothermic with the Bair Hugger as opposed to not using anything, which was the standard of care at that point in time. Q. Okay. Well when you say "not using anything," you'd use blankets. A. Yeah, operating room blankets, yeah.
2 3 4 5 6 7	 Q. At any point? A. I was, yes. Q. Okay. And did any discussion during this period of time in the decision making deal with the efficacy of the Mistral system as compared to the Bair Hugger system? A. Yes. 	2 3 4 5 6 7	A. We did the very first — one of the first Bair Hugger studies in Europe looking at whether one can keep patients normothermic with the Bair Hugger as opposed to not using anything, which was the standard of care at that point in time. Q. Okay. Well when you say "not using anything," you'd use blankets.
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4 (Pages 13 to 16)

	Page 17		Page 19
1	A. I think by coincidence. It was just that	1	A. Uh-huh.
2	forced-air warming was introduced at the University of	. 2	Q on the last one there, it's "Fellowship,
3	Vienna, and whenever you I wanted to do research,	3	Augustine Medical, \$100,000." Do you see that?
4	and whenever you introduce a new system, you study it	. 4	A. Uh-huh.
5	first, and I I guess it was probably one of my	5	THE REPORTER: Your answer?
6	mentors there that suggested that I would participate	6	MR. ASSAAD: Is that a yes?
7	in that study.	7	MS. DIFRANCO: Yes.
8	Q. Did you lead the study? Were you	8	THE WITNESS: Yes.
9	A. Yes.	. 9	Q. Okay. What was that for?
10	Q. Okay. How was	10	A. '94. I don't exactly know. It was during
11	Do you recall how forced-air warming or	11	my fellowship, so they might have supported the
12	who introduced forced-air warming, the Bair Hugger	12	fellowship at the lab there. But I can't remember
13	system, to the University of Vienna?	13	exactly.
14	A. Yes, I do.	14	Q. Okay. Did this have anything to do with any
15	Q. Who?	15	type of funding for your 1996 New England Journal of
16	A. It was a company that is called or was	16	Medicine study?
17	called Gepa-Med, G-e-p-a-Med.	17	A. No.
18	Q. Okay. And to your recollection, was that	. 18	Q. Well you agree that if it
19	the first time that forced-air warming was used	19	It was most likely for funding or sponsoring
20	intraoperatively?	20	research for normothermia and forced-air warming.
21	A. Yes. In Austria.	21	A. It was for funding research for physiology
22	Q. In Austria, okay. And GepaMed or whatever	22	in regards to normothermia.
23	the name	23	Q. Was any paper published as a result of this
24	A. GepaMed.	24	funding?
O.F	. O Whose is that assuments from ?	I	
25	Q. Where is that company from? Page 18	25	A. I assume that there were many papers Page 20
1	Page 18 A. Vienna.	25	Page 20 published as a result. I published about, I can't
1 2	Page 18 A. Vienna. Q. Vienna. Okay.	1 2	Page 20 published as a result. I published about, I can't remember, 15 papers during these three years.
1 2 3	Page 18 A. Vienna. Q. Vienna. Okay. Did there ever come a time that you had	1 2 3	Page 20 published as a result. I published about, I can't remember, 15 papers during these three years. Q. And during those three years, did you have a
1 2 3 4	Page 18 A. Vienna. Q. Vienna. Okay. Did there ever come a time that you had dealings with Augustine Medical?	1 2 3	Page 20 published as a result. I published about, I can't remember, 15 papers during these three years.
1 2 3 4 5	Page 18 A. Vienna. Q. Vienna. Okay. Did there ever come a time that you had dealings with Augustine Medical? A. Yes.	1 2 3 4 5	Page 20 published as a result. I published about, I can't remember, 15 papers during these three years. Q. And during those three years, did you have a clinical practice as well? A. No.
1 2 3 4 5	Page 18 A. Vienna. Q. Vienna. Okay. Did there ever come a time that you had dealings with Augustine Medical? A. Yes. Q. When was the first time that you had any	1 2 3 4 5 6	Page 20 published as a result. I published about, I can't remember, 15 papers during these three years. Q. And during those three years, did you have a clinical practice as well? A. No. Q. It was pure research?
1 2 3 4 5 6	Page 18 A. Vienna. Q. Vienna. Okay. Did there ever come a time that you had dealings with Augustine Medical? A. Yes. Q. When was the first time that you had any type of interactions with Augustine Medical?	1 2 3 4 5 6 7	Page 20 published as a result. I published about, I can't remember, 15 papers during these three years. Q. And during those three years, did you have a clinical practice as well? A. No. Q. It was pure research? A. Yes.
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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Vienna. Q. Vienna. Okay. Did there ever come a time that you had dealings with Augustine Medical? A. Yes. Q. When was the first time that you had any type of interactions with Augustine Medical? A. It— I don't know exactly. It might have been during that study, or after I started my fellowship in San Francisco. Q. And is that when you first met Scott Augustine? A. Yes. Q. Okay. Did you meet Scott Augustine in — in Vienna or in San Francisco for the first time? A. I think in San Francisco. Q. Okay. That would be around 1993? A. I cannot remember the year, but— Q. Okay. A. — during that timeframe. Q. Okay. And on your CV on page 17—	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	published as a result. I published about, I can't remember, 15 papers during these three years. Q. And during those three years, did you have a clinical practice as well? A. No. Q. It was pure research? A. Yes. Q. This hundred thousand dollars, was this money that went into your pocket or went towards the univer towards the university? A. It went towards the university. Q. Your New England Journal of Medicine article Medicine article of 1996, was that funding from peer-review or corporate sponsors for that research, do you recall? A. I don't. I don't. That must have been The study happened in Vienna, and so I assume we had barely any funding for that study Q. Okay. A at that point in time. Q. Do you know whether or not Augustine Medical was involved in any way in that study?

5 (Pages 17 to 20)

I'm going to call it the Kurz study of 1996.	ł	
Thi going to can it the Kurz study of 1990.	. 1	spine in the neck area vasodilates the periphery
A. That is totally fine.	2	and and therefore the periphery, meaning hands and
Q. Huh?	. 3	feet, are easier to warm.
A. That is fine.	4	Q. Okay. And the inventor of that technology
Q. In your 1996 Kurz study, the Kurz study,	5	is Dr. Diller; correct?
were you the lead	6	A. Yes.
A. Yes, I was.	7	Q. Okay. And it's my understanding that
Q researcher?	8	there's already been one clinical trial that it has
A. Uh-huh.	9	gone through.
Q. Yes?	10	A. There's been one observational study, yes.
A. Yes.	11	Q. Okay. And are there is there a plan
Q. Okay. What role did Dr. Sessler have in the	12	Is there any plans for another study?
1996 Kurz study?	13	A. There is a plan for a volunteer study, yes.
A. He was a senior researcher, so he was my	. 14	Q. Okay. And what were the results of the
mentor.	15	first observational study?
Q. Did he have any strike that. Withdraw.	16	A. Unclear.
Going to page	17	Q. Why do you say "unclear?"
the contract of the contract o	1,8	A. Because we evaluated in patients vasomotion
consult for 3M?	19	in the per
A. Yes.	20	So we wanted to show in patients under
	21	anesthesia whether spine warming truly causes
A. I don't know exactly. Three, four years,	22	vasodilation, and under anesthesia many other things
five years.	23	have been other than warming, so it's
Q. Have you ever consulted for Arizant Medical?	24	The data at this point is very hard to
A. I don't remember. I might.	25	evaluate and that's why I say it's unclear. It's just
Page 22	-	Page 24
O. Who else do you do consulting services for	1	that patients who are diabetic react differently,
	2	patients who need vasopressors react vaso react
· -	. 3	differently, so I think it's uninterpretable.
here in Cleveland.	4	Q. Okay. And is Dr. Sessler also on the
Q. Mercury Biomed?	5	advisory board for Mercury Biomed?
A. Yes.	6	A. I believe so.
Q. And it's my understanding that they're in	7	Q. Okay. So currently my understanding is
	8	you're on the advisory board or panel for 3M and
	9	Mercury Biomed; correct?
A. I heard about that.	10	A. Yes.
Q. And that's how you received documents with	11	Q. How about in the past, who have you been on
respect some due diligence documents to review	12	the advisory board for?
from from the company that that was acquiring	13	A. Good question.
Mercury Biomed. Do you recall that?	14	Q. Well we know 37Company is one of them;
A. No, I did not.	15	correct?
Q. It's documents that you produced to me, but	16	A. We know 37Company. You know, I I don't
it's irrelevant.	17	think I recall anything else.
And what technology do they have? Do they	18	Q. VitaHEAT?
deal with warming patients?	19	A. Vital
A. Yes, they do.	20	Q. VitaHEAT.
Q. And what technology do they have?	21	A. No.
	22	Q. Okay.
	23	A. Which company is that?
•	24	Q. That's its own company, VitaHEAT.
spine warming part with the idea that warming the	25	A. Okay.
	A. That is fine. Q. In your 1996 Kurz study, the Kurz study, were you the lead A. Yes, I was. Q researcher? A. Uh-huh. Q. Yes? A. Yes. Q. Okay. What role did Dr. Sessler have in the 1996 Kurz study? A. He was a senior researcher, so he was my mentor. Q. Did he have any strike that. Withdraw. Going to page Well before we get there, do you currently consult for 3M? A. Yes. Q. How long have you consulted for 3M? A. I don't know exactly. Three, four years, five years. Q. Have you ever consulted for Arizant Medical? A. I don't remember. I might. Page 22 Q. Who else do you do consulting services for or on the advisory panel for? A. Currently, only one other company that is here in Cleveland. Q. Mercury Biomed? A. Yes. Q. And it's my understanding that they're in the process of or negotiating a process of being purchased by another company. A. I heard about that. Q. And that's how you received documents with respect some due diligence documents to review from from the company that that was acquiring Mercury Biomed. Do you recall that? A. No, I did not. Q. It's documents that you produced to me, but it's irrelevant. And what technology do they have? Do they deal with warming patients? A. Yes, they do. Q. And what technology do they have? A. It's a it's a conductive warming system by warming hands and feet; however, it also has a a a second physiological thing to it, it has a	A. That is fine. Q. In your 1996 Kurz study, the Kurz study, were you the lead A. Yes, I was. Q researcher? A. Uh-huh. Q. Yes? A. Yes. Q. Okay. What role did Dr. Sessler have in the 1996 Kurz study? A. He was a senior researcher, so he was my mentor. Q. Did he have any strike that. Withdraw. Going to page Well before we get there, do you currently consult for 3M? A. Yes. Q. How long have you consulted for 3M? A. I don't know exactly. Three, four years, five years. Q. Have you ever consulted for Arizant Medical? A. I don't remember. I might. Page 22 Q. Who else do you do consulting services for or on the advisory panel for? A. Currently, only one other company that is here in Cleveland. Q. Mercury Biomed? A. Yes. Q. And it's my understanding that they're in the process of or negotiating a process of being purchased by another company. A. I heard about that. Q. And that's how you received documents with respect some due diligence documents to review from from the company that that was acquiring Mercury Biomed. Do you recall that? A. No, I did not. Q. It's documents that you produced to me, but it's irrelevant. And what technology do they have? Do they deal with warming patients? A. Yes, they do. Q. And what technology do they have? A. It's a it's a conductive warming system by warming hands and feet; however, it also has a a a second physiological thing to it, it has a

6 (Pages 21 to 24)

	Page 25		Page 27
1	Q. What about PerfecTemp for	1	(Discussion off the stenographic record.)
2	A. No, I don't even know.	2	(Exhibit 238 was marked for
. 3	Q. Medline?	3	identification.)
4	A. Medline?	4	BY MR. ASSAAD:
5	Q. Uh-huh.	5	Q. What's been marked as 238 is an article
6	A. No.	6	written by you and Dr. Sessler entitled "Departmental
7	Q. Okay. So anyone else that you can think of	7	and Institutional Strategies for Reducing Fraud in
8	that deals with patient warming?	8	Clinical Research."
9	A. No.	9	A. Uh-huh.
10	Q. Now going back to your funded research, you	10	Q. Do you recall this article?
11	break it up into peer-reviewed sources and corporate	11	A. Yes.
12	sources; correct?	12	Q. If you look at page 475,
13	A. Uh-huh.	13	A. I see that.
14	Q. Yes?	14	Q at the second column, second
15	A. Yes.	15	A. Uh-huh.
16	Q. Why do you do that? What's the difference?	16	Q paragraph, starts with, "The risk of
17	A. There is	17	fraud is probably greater for investigator-initiated
18	First of all, it's the way how you or how	18	studies than for trials conducted by corporate
19	we, at least in the medical field, write our CVs.	19	sponsors." Do you see that?
20	There's a very different review process and	20	A. Yes, I do see that.
21	negotiation process with corporate and peer-reviewed	21	Q. What did you mean by that?
22	sources, and so I guess all the peer-reviewed ones are	22	A. It actually says thereafter
23	considered to be on a higher scientific level.	23	Anyway, the the reason is the sponsors
2.4	Q. The peer reviewed?	24	have legal obligations to assure that the valid
25	A. Yeah. And that's why you want to know	25	validity of the data is correct. And if you read the
	Page 26		Page 28
1	whether an investigator has only corporate funding or	1	beginning of the article, it describes our structure
2	mainly peer-reviewed funding.	2	in the Outcomes Research department here, and it does
. 3	Q. But I recall you wrote an article that peer-	3	say that in previous times when single people would do
4	reviewed funding is also the most susceptible to	4	a study completely by themselves, that they wouldn't
5	fraud.	5	knowledgeably do fraudulent work, but they would
6	A. Peer-reviewed funding?	6	maybe not always abide to strict rules of
7	Q. Uh-huh.	7	randomization, blinding, et cetera, and that's
8	A. I don't think I said that.	8	that's what's meant by that, and therefore, we at the
9	Q. Or or research, research initiated by	9	Outcomes Research department have all the structures
10	investigators as compared to which is more peer	10	to avoid this kind of thing.
11	peer-reviewed, as compared to corporate is more	11	Q. Whether it's
12	susceptible to fraud. Is that true?	12	A. Whether it's
13	A. I think I wouldn't phrase it that way, and I	13	Q peer investi or investigator or
	would be surprised that I phrased it exactly that way.	14	corporate.
14		15	A. Yes.
14 15	Q. And I could be misquoting and I I'll pull		O F-1
	up the article.	16	Q. Fair enough.
15	· · · · · · · · · · · · · · · · · · ·	16 17	On on the disclosures it says, "This
15 16	up the article.		<u> </u>
15 16 17	up the article. A. No, you are right. I wrote an article, but	17	On on the disclosures it says, "This
15 16 17 18	up the article. A. No, you are right. I wrote an article, but it would be great if you had it because I don't think	17 18	On – on the disclosures it says, "This manuscript was handled by: Steven L. Shafer M.D." Do
15 16 17 18 19	up the article. A. No, you are right. I wrote an article, but it would be great if you had it because I don't think I said it that way. I think what we might what I	17 18 19	On — on the disclosures it says, "This manuscript was handled by: Steven L. Shafer M.D." Do you know who that is?
15 16 17 18 19 20	up the article. A. No, you are right. I wrote an article, but it would be great if you had it because I don't think I said it that way. I think what we might what I might have said	17 18 19 20	On — on the disclosures it says, "This manuscript was handled by: Steven L. Shafer M.D." Do you know who that is? A. Yes. He was at that point in time the
15 16 17 18 19 20 21	up the article. A. No, you are right. I wrote an article, but it would be great if you had it because I don't think I said it that way. I think what we might what I might have said MS. DIFRANCO: Why don't you wait.	17 18 19 20 21	On — on the disclosures it says, "This manuscript was handled by: Steven L. Shafer M.D." Do you know who that is? A. Yes. He was at that point in time the editor of the journal Anesthesia & Analgesia.
15 16 17 18 19 20 21	up the article. A. No, you are right. I wrote an article, but it would be great if you had it because I don't think I said it that way. I think what we might what I might have said MS. DIFRANCO: Why don't you wait. THE WITNESS: Yeah.	17 18 19 20 21 22	On — on the disclosures it says, "This manuscript was handled by: Steven L. Shafer M.D." Do you know who that is? A. Yes. He was at that point in time the editor of the journal Anesthesia & Analgesia. Q. Okay. Is he a friend of Dr. Sessler's?

7 (Pages 25 to 28)

1	Page 29		Page 31
1	Sorry, go ahead.	1	question.
2	A. Whether they're friends, I don't know.	2	Q. Let me rephrase. It was a bad question.
3	Q. Okay. And when it says, "This manuscript	3	A. I'm not sure. Yeah.
4	was handled by: Steven L. Shafer," what part of it	4	Q. Is corporate-funded research let me ask
5	was he involved in?	5	it more openly.
6	A. He is edit editor of Anesthesia &	6	A. Uh-huh.
7	Analgesia. He gets all articles that are submitted to	7	Q. Why would corporate-funded research not be
8	the journal and then either hands them on to other	8 -	at such a high level as peer-reviewed research?
9	editors or deals with them himself.	9	A. I said I might consider it not as high.
10	Q. I I understand that, but	10	Q. In your opinion then.
11	And maybe I just don't know. But I've seen	11	A. In my opinion. Ideally, corporate-funded
12	other articles in other peer-reviewed publications and	12	research will be scientifically at the exact same
1.3	I've never seen anything where it says the manuscript	13	level as any other type of research.
14	was handled by the like the editor in chief or the	14	Q. Do you agree with me that some corporate-
15	main editor of of the of the publication. Why	15	funded research is commercially motivated?
16	is it different in this publication as compared to	16	A. I agree.
·17	other publications?	17	Q. And in fact would you agree that most
18	MR. GORDON: Object to the form of the	18	corporate-funded research has some sort of commercial
19	question.	19	motivation?
20	MS. DIFRANCO: Go ahead, if you know.	20	MR. GORDON: Object to the form of the
21	A. I no, I don't know. I can	21	question, also lack of foundation.
22	I think it is because it's an open-mind	22	MS. DIFRANCO: Go ahead and answer.
23	article. This is not a research paper,	23	A. I would say some of it is. I don't want to
24	Q. Okay.	24	say most of it is.
25	A this is just an opinion.	25	Q. Can you sit here today and identify one
	· ·		
	Page 30	•	Page 32
1	Q. Fair enough.	1	company that has that you've received research from
2	Q. Fair enough.MS. DIFRANCO: And doctor, I think Mr.	2	company that has that you've received research from that didn't deal with any type of product or
l	Q. Fair enough. MS. DIFRANCO: And doctor, I think Mr. Assaad wants to know what you know. If you don't know	2 3	company that has that you've received research from that didn't deal with any type of product or technology or anything with the with the company
2 3 4	Q. Fair enough. MS. DIFRANCO: And doctor, I think Mr. Assaad wants to know what you know. If you don't know something, you just tell him that's what	2 3 4	company that has that you've received research from that didn't deal with any type of product or technology or anything with the with the company business?
2 3 4 5	Q. Fair enough. MS. DIFRANCO: And doctor, I think Mr. Assaad wants to know what you know. If you don't know something, you just tell him that's what THE WITNESS: Uh-huh.	2 3 4 5	company that has that you've received research from that didn't deal with any type of product or technology or anything with the with the company business? A. I don't think so.
2 3 4 5 6	Q. Fair enough. MS. DIFRANCO: And doctor, I think Mr. Assaad wants to know what you know. If you don't know something, you just tell him that's what THE WITNESS: Uh-huh. MS. DIFRANCO: He doesn't want you to guess.	2 3 4 5 6	company that has that you've received research from that didn't deal with any type of product or technology or anything with the with the company business? A. I don't think so. Q. So you agree with me that the majority of
2 3 4 5 6	Q. Fair enough. MS. DIFRANCO: And doctor, I think Mr. Assaad wants to know what you know. If you don't know something, you just tell him that's what THE WITNESS: Uh-huh. MS. DIFRANCO: He doesn't want you to guess. MR. ASSAAD: I don't want you to guess or	2 3 4 5 6 7	company that has that you've received research from that didn't deal with any type of product or technology or anything with the with the company business? A. I don't think so. Q. So you agree with me that the majority of corporate-funded research has some sort of commercial
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	Page 33	Page 35
1	over the past 25 years, so what was standard of care	1 unfavorable for the cor for the the research
2	in the clinical world what was standard of care 20	2 that was being done that was funded by a corporate
3	years ago, was absolutely correct then, might not be	3 sponsor
4	now.	4 A. Uh-huh.
5	Q. Okay. But sitting here today, you stand	5 Q and request the com and and stop
. 6	by you stand behind all your publications; correct?	6 further research as a result of a request of a
7	A. Absolutely.	7 corporate sponsor?
. 8	Q. Okay. Are there any publications dealing	8 A. That might have been.
9	with forced normothermia that sitting here today	9 Q. Do you recall any specific instance?
10	withdraw that question.	10 A. It is things that usually have been in
11	For example, the 1996 Kurz study that was	product development. So, for example, when we worked
12	done by you, would that comply with today's standards	12 with with a company like Mercury, who was
13	with regard to departmental and institutional	13 developing a product, and we get it here, do a study,
14	strategies for reducing fraud in clinical research	14 and we see that it's not working because the product
15	outlined in Exhibit 238?	15 isn't yet developed in a way, then we agree to stop,
16	A. I actually believe so.	16 get it better developed, and do the study.
17	Q. You hesitated. Why was that? You say you	17 Q. Okay.
18	absolutely believe so. Is there	18 A. So
19	A. Yeah. Because it was done under very	19 But that's more product development side.
20	different circumstances.	20 Q. Has 3M ever asked you, in any publications
21	Q. Okay. In any of your research or	21 you've ever done for them, to that they want to
22	publications that were corporately funded by	22 make changes to the manuscript before you submit it
23	corporations, do you allow those corporations to have	23 for publication?
24	any editorial input with respect to publications?	24 A. I believe once.
25	A. We allow, per contract, all the companies to	25 Q. Can you please describe that.
	Page 34	Page 36
1	read the publications and to before we publish it.	1 1 Thomas and a first Transition 1
2		A. I'm not certain that I completely remember.
_	That's a Cleveland Clinic rule.	1 A. I'm not certain that I completely remember. 2 It was a it was a in a retrospective study about
3	That's a Cleveland Clinic rule. O. Do you allow them to make changes?	2 It was a it was a in a retrospective study about
	Q. Do you allow them to make changes?	2 It was a it was a in a retrospective study about 3 the effect of hypothermia on perioperative blood loss
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9 (Pages 33 to 36)

	Page 37		Page 39
1	comparison study of vital HEAT (vH2) Temperature	1	A. Yes.
2	Management System to upper-body forced-air warming in	2 ·	Q. Can you point to me the paper?
3	patients undergoing open colectomy under general	3	A. Yeah. Two eight nine, two eight nine.
4	anesthesia." Do you see that?	4	Who was the first author? Yeah, number 102,
5	A. Yes, I do.	5	"Normothermia During "Maintain Normothermia
6	Q. And I guess the principal investigator is	6	During Open Abdominal Surgery."
7	Dr. Sessler.	7	Q. Okay. And just to be clear, are you saying
. 8	A. Uh-huh,	8	that it was as effective as forced-air warming, or
9	THE REPORTER: Your answer?	9	you because it says "Comparably." What does that
10	Q. Yes?	10	mean to you?
11	A. Yes.	11	A. That would mean as effective, yeah.
12	Q. And the company is LMA?	12	Q. Okay. Also on page 16, second one is "LMA-
13	A. Yes.	13	Perfect temperature versus Forced air warming,"
14	Q. Do you know who LMA is, or what that stands	14	principal investigator was Dr. Sessler, company was
15	for?	15	LMA North America, you received \$196,000 for that
16	A. I can't remember, no.	16	study. Do you recall that study?
17	Q. Okay. Do you recall doing this research	17	A. Not clearly.
18	for on the on the vital HEAT?	18	Q. Okay. Do you know what year that was?
19	A. I do.	19	Because the year is missing.
20 .	Q. Okay. And you received \$250,000 to conduct	20	A. They are in in ascending order, so
21	the research; correct?	21	it must have been around 2012.
22	A. Yes.	22	Q. And let me ask you if it's if it's
23	Q. And also it's in 2008 and 2009; correct?	23	article number 97.
24	A. I assume.	24	A. I'll look.
25	Q. Okay. What do you recall about this	25	No.
		,	Page 40
1	research?	1	Q. Okay.
2	A. I think this was a study and I would have	- 2	Q. Okay. A. Huh-uh.
2	A. I think this was a study and I would have to look it up that was performed	3	Q. Okay. A. Huh-uh. Q. Oh.
2 3 4	A. I think this was a study and I would have to look it up that was performed Vital HEAT. You know what? I have to guess	2 3 4	Q. Okay.A. Huh-uh.Q. Oh.A. Because that's too early.
2 3 4 5	A. I think this was a study and I would have to look it up that was performed Vital HEAT. You know what? I have to guess now, so no.	2 3 4 5	 Q. Okay. A. Huh-uh. Q. Oh. A. Because that's too early. Q. Okay. If you don't know, that's fine, we
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. I think this was a study and I would have to look it up that was performed Vital HEAT. You know what? I have to guess now, so no. Q. Okay. Do you know do you know what the vital HEAT Temperature Management System is? A. I do know what it is. Q. What is it? A. It was an arm/hand warming system that applied heat and negative pressure to an arm. Q. Just one arm? A. Yes. Q. Okay. And what were Do you recall the results of that study? A. I believe it was almost as effective as forced air. Q. Okay. And that didn't blow any air; correct? A. Hmm?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. Okay. A. Huh-uh. Q. Oh. A. Because that's too early. Q. Okay. If you don't know, that's fine, we can we can move on. A. Uh-huh. Q. And finally, going to page 15, I have a couple couple of other questions. The second one down is "Core temperature profiles at the Cleve at the Cleveland Clinic," sponsored by 3M, \$75,000. A. Uh-huh. Q. Do you recall Is that yes? A. Yes. Q. Do you recall that study? A. Yes. Q. What study is that? A. That only describes, as it says, core temperature profiles in something like 50,000 patients
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. I think this was a study and I would have to look it up that was performed Vital HEAT. You know what? I have to guess now, so no. Q. Okay. Do you know do you know what the vital HEAT Temperature Management System is? A. I do know what it is. Q. What is it? A. It was an arm/hand warming system that applied heat and negative pressure to an arm. Q. Just one arm? A. Yes. Q. Okay. And what were Do you recall the results of that study? A. I believe it was almost as effective as forced air. Q. Okay. And that didn't blow any air; correct? A. Hmm? Q. It didn't blow any air. It wasn't forced	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Okay. A. Huh-uh. Q. Oh. A. Because that's too early. Q. Okay. If you don't know, that's fine, we can we can move on. A. Uh-huh. Q. And finally, going to page 15, I have a couple couple of other questions. The second one down is "Core temperature profiles at the Cleve at the Cleveland Clinic," sponsored by 3M, \$75,000. A. Uh-huh. Q. Do you recall Is that yes? A. Yes. Q. Do you recall that study? A. Yes. Q. What study is that? A. That only describes, as it says, core temperature profiles in something like 50,000 patients that have been operated at the Cleveland Clinic over
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. I think this was a study and I would have to look it up that was performed Vital HEAT. You know what? I have to guess now, so no. Q. Okay. Do you know do you know what the vital HEAT Temperature Management System is? A. I do know what it is. Q. What is it? A. It was an arm/hand warming system that applied heat and negative pressure to an arm. Q. Just one arm? A. Yes. Q. Okay. And what were Do you recall the results of that study? A. I believe it was almost as effective as forced air. Q. Okay. And that didn't blow any air; correct? A. Hmm? Q. It didn't blow any air. It wasn't forced A. No.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Okay. A. Huh-uh. Q. Oh. A. Because that's too early. Q. Okay. If you don't know, that's fine, we can we can move on. A. Uh-huh. Q. And finally, going to page 15, I have a couple couple of other questions. The second one down is "Core temperature profiles at the Cleve at the Cleveland Clinic," sponsored by 3M, \$75,000. A. Uh-huh. Q. Do you recall Is that yes? A. Yes. Q. Do you recall that study? A. Yes. Q. What study is that? A. That only describes, as it says, core temperature profiles in something like 50,000 patients that have been operated at the Cleveland Clinic over the past about eight years.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. I think this was a study and I would have to look it up that was performed Vital HEAT. You know what? I have to guess now, so no. Q. Okay. Do you know do you know what the vital HEAT Temperature Management System is? A. I do know what it is. Q. What is it? A. It was an arm/hand warming system that applied heat and negative pressure to an arm. Q. Just one arm? A. Yes. Q. Okay. And what were Do you recall the results of that study? A. I believe it was almost as effective as forced air. Q. Okay. And that didn't blow any air; correct? A. Hmm? Q. It didn't blow any air. It wasn't forced A. No. Q. Okay,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. Okay. A. Huh-uh. Q. Oh. A. Because that's too early. Q. Okay. If you don't know, that's fine, we can — we can move on. A. Uh-huh. Q. And finally, going to page 15, I have a couple — couple of other questions. The second one down is "Core temperature profiles at the Cleve — at the Cleveland Clinic," sponsored by 3M, \$75,000. A. Uh-huh. Q. Do you recall — Is that yes? A. Yes. Q. Do you recall that study? A. Yes. Q. What study is that? A. That only describes, as it says, core temperature profiles in something like 50,000 patients that have been operated at the Cleveland Clinic over the past about eight years. Q. Is that research still ongoing?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. I think this was a study and I would have to look it up that was performed Vital HEAT. You know what? I have to guess now, so no. Q. Okay. Do you know do you know what the vital HEAT Temperature Management System is? A. I do know what it is. Q. What is it? A. It was an arm/hand warming system that applied heat and negative pressure to an arm. Q. Just one arm? A. Yes. Q. Okay. And what were Do you recall the results of that study? A. I believe it was almost as effective as forced air. Q. Okay. And that didn't blow any air; correct? A. Hmm? Q. It didn't blow any air. It wasn't forced A. No.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Okay. A. Huh-uh. Q. Oh. A. Because that's too early. Q. Okay. If you don't know, that's fine, we can we can move on. A. Uh-huh. Q. And finally, going to page 15, I have a couple couple of other questions. The second one down is "Core temperature profiles at the Cleve at the Cleveland Clinic," sponsored by 3M, \$75,000. A. Uh-huh. Q. Do you recall Is that yes? A. Yes. Q. Do you recall that study? A. Yes. Q. What study is that? A. That only describes, as it says, core temperature profiles in something like 50,000 patients that have been operated at the Cleveland Clinic over the past about eight years.

10 (Pages 37 to 40)

	Page 41		Page 43
1	A. Yes, it has been published.	1	satisfaction in patients undergoing ambulatory
2	Q. Is that the 2015 publication in	2	surgery," \$150,000 from 37Company.
3	Anesthesiology?	3	A. Yes.
4	A. Yes.	4	Q. Okay. And has that study been published?
5	Q. Fair enough.	5	A. Yes.
6	A. Yes.	6	Q. And what was
7	Q. And if I recall correctly, it also looked at	7	A. Oh, I think it is in publication.
8	blood loss.	8	Q. Can you describe that study, please?
9	A. Yes.	9	A. In this study, patients were warmed before
1.0	Q. Okay. And I take it during the blood loss	10	induction of anesthesia in an ambulatory setting, with
11	you discussed Celsius hours; correct?	11	the idea that patients who were warmer before surgery
12	A. Correct, yes.	12	will have better patient satisfaction afterwards.
13	Q. Okay. And I	13	Q. So prewarming.
14	My understanding of Celsius hours is how	14	A. Prewarming.
15	many degrees below 37 degrees multiplied by how many	15	Q. Okay. Now with respect to your articles, do
16	hours are at that time period.	16	you do you publish any particles or any articles
17	A. Exactly.	17	listed in areas that you have no expertise in?
18	Q. Okay. And that was predictive of the	18	A. No.
19	risk the the risk rate of blood loss; correct?	19	Q. Okay. Would that be would that be sort
20	A. Not blood loss, but transfusions.	20	of a fraud if you published something that you have no
21	Q. Transfusions. I'm sorry, you're correct.	21	expertise in?
22	And if I recall correctly, in that study you	22	MR. GORDON: Object to the form of the
23	also looked at length of stay, but that the results	23	question.
24	were not statistically significant; correct?	24	MR. ASSAAD: He may object,
25	A. That's	25	MS. DIFRANCO: Yeah, go ahead.
1	Yes.	1	MR. ASSAAD: but you may answer.
2	Q. Below that you have "Target Normothermia." That's also sponsored by 3M?	. 1 ·2 3	MR. ASSAAD: but you may answer. MS. DIFRANCO: I'll tell you if you shouldn't.
2	Q. Below that you have "Target Normothermia."	.2	MS. DIFRANCO: I'll tell you if you
2 3	Q. Below that you have "Target Normothermia."That's also sponsored by 3M?A. Uh-huh. Yes.	2 3	MS. DIFRANCO: I'll tell you if you shouldn't. A. No, it would not, because you could still
2 3 4	Q. Below that you have "Target Normothermia." That's also sponsored by 3M?	2 3 4	MS. DIFRANCO: I'll tell you if you shouldn't.
2 3 4 5	 Q. Below that you have "Target Normothermia." That's also sponsored by 3M? A. Uh-huh. Yes. Q. You're catching on. 	2 3 4 5.	MS. DIFRANCO: I'll tell you if you shouldn't. A. No, it would not, because you could still have some input into a paper. It's just that I do not
2 3 4 5 6	 Q. Below that you have "Target Normothermia." That's also sponsored by 3M? A. Uh-huh. Yes. Q. You're catching on. What's that study about? 	2 3 4 5. 6	MS. DIFRANCO: I'll tell you if you shouldn't. A. No, it would not, because you could still have some input into a paper. It's just that I do not do that.
2 3 4 5 6 7	 Q. Below that you have "Target Normothermia." That's also sponsored by 3M? A. Uh-huh. Yes. Q. You're catching on. What's that study about? A. That study 	2 3 4 5 6 7	MS. DIFRANCO: I'll tell you if you shouldn't. A. No, it would not, because you could still have some input into a paper. It's just that I do not do that. Q. Oh. Why don't you do it?
2 3 4 5 6 7 8	 Q. Below that you have "Target Normothermia." That's also sponsored by 3M? A. Uh-huh. Yes. Q. You're catching on. What's that study about? A. That study That actually is not a study, it's a qual 	2 3 4 5 6 7 8	MS. DIFRANCO: I'll tell you if you shouldn't. A. No, it would not, because you could still have some input into a paper. It's just that I do not do that. Q. Oh. Why don't you do it? A. Because I feel more comfortable with things
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2 3 4 5 6 7 8 9 10 11 12	 Q. Below that you have "Target Normothermia." That's also sponsored by 3M? A. Uh-huh. Yes. Q. You're catching on. What's that study about? A. That study That actually is not a study, it's a qual it was a quality-improvement project about looking at There were, if I know now, about 60 institutions in various different countries that 	2 3 4 5. 6 7 8 9 10 11	MS. DIFRANCO: I'll tell you if you shouldn't. A. No, it would not, because you could still have some input into a paper. It's just that I do not do that. Q. Oh. Why don't you do it? A. Because I feel more comfortable with things I know things about. Q. Have you ever published a paper or worked on a paper as a favor for a corporation? A. No.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Below that you have "Target Normothermia." That's also sponsored by 3M? A. Uh-huh. Yes. Q. You're catching on. What's that study about? A. That study That actually is not a study, it's a qual it was a quality-improvement project about looking at There were, if I know now, about 60 institutions in various different countries that measured core temperature over a three-month period, and then we evaluated just in an observational fashion the incidence of hypothermia. (Discussion off the stenographic record.) Q. I think I recall that, and that's where you had a bunch of graphs with each country; correct? A. Exactly. Q. Okay. A. Yes. Q. I can't find it now, but I do recall that.	12 3 4 5. 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MS. DIFRANCO: I'll tell you if you shouldn't. A. No, it would not, because you could still have some input into a paper. It's just that I do not do that. Q. Oh. Why don't you do it? A. Because I feel more comfortable with things I know things about. Q. Have you ever published a paper or worked on a paper as a favor for a corporation? A. No. Q. Why not? A. Because I I like doing the research myself, so Q. Okay. Have you ever edited a paper that was written by a corporation and put your name on it to get it published? A. Not for publication. Q. Would you ever put your name on a paper that you weren't involved in with respect to the protocols with respect in beginning the research?

11 (Pages 41 to 44)

ı	Page 45	,	Page 47
1	that you really have a substantial intellectual	1	Sessler about the deposition?
2	contribution to a study, so	2	A. No.
3	Well let me rephrase that. I might put my	3	Q. Have you had any discussions with Dr.
4	name on a paper where I have significant contribution.	4	Sessler about this case?
5	Q. Okay. In an area that you have expertise	5	A. Minimally.
6	in.	6	Q. Do you know what this case is about?
7	A. Yes.	7.	A. Yes, I do.
8	Q. Okay. Under your authors' ethics in doing	8	Q. What's your understanding of of the
9	research, is it ethical to have to have the	9	claims in this case?
10	corporation write the first draft of the manuscript in	10	A. My understanding is that 3M or or
11	corporate-sponsored funding?	11	or that there is a lawsuit against 3M in regards to
12	A. In corporate I	12	bacterial contamination of patients undergoing
13	Under mine, I assume not.	13	orthopedic surgery, I guess hip replacements, due to
14	Q. Why not?	14	bacteria generated and blown around by forced-air
15	A. Just because if if I do research, I I	15	warming.
16	think I want it written in my words.	16	Q. You have no expertise in in operating
17	Q. Fair enough.	17	room airflow; correct?
1.8	And in any of your research or publications,	18	A. No. No.
19	has there ever been an instance in which the first	19	Q. And you have no expertise in orthopedic
20	draft of the manuscript was provided to you by the	20	surgery; correct?
21	corporation that sponsored the study?	21	A. No.
22	A. I don't think so.	22	Q. Do you have any expertise in periprosthetic
23	Q. Have you ever done research sponsored by a	23	joint infections?
24	corporation that the outcome was a disappointing	24	A. No.
25	clinical result for the corporation?	25	Q. Do you have any expertise with respect to
	Page 46		Page 48
. 1	A. I can't recall. I might have. I can't	. 1	the causation of periprosthetic joint infections?
2	recall	2	A. No.
3	Q. I mean in all the	3	Q. Do you have an understanding that
4.	A a study now.	4	periprosthetic joint infections are different than
5	Q. I mean in all the studies that you've	5	a a soft-tissue wound infection?
6	performed that were corporate sponsored, has there		
		6	A. Yes.
7	ever been a study which the result was not favorable	7	Q. Okay. I assume you're familiar with host
7	ever been a study which the result was not favorable to the corporate sponsor?	7 8	Q. Okay. I assume you're familiar with host defense
7 8 9	ever been a study which the result was not favorable to the corporate sponsor? A. Probably.	7 8 9	Q. Okay. I assume you're familiar with host defense A. Yes.
7 8 9 10	ever been a study which the result was not favorable to the corporate sponsor? A. Probably. Q. Okay. And	7 8 9 10	 Q. Okay. I assume you're familiar with host defense A. Yes. Q dealing with normothermia; correct?
7 8 9 10 11	ever been a study which the result was not favorable to the corporate sponsor? A. Probably. Q. Okay. And But you don't know one way or the other?	7 8 9 10 11	 Q. Okay. I assume you're familiar with host defense A. Yes. Q dealing with normothermia; correct? A. Uh-huh.
7 8 9 10 11 12	ever been a study which the result was not favorable to the corporate sponsor? A. Probably. Q. Okay. And But you don't know one way or the other? A. Correct.	7 8 9 10 11 12	 Q. Okay. I assume you're familiar with host defense A. Yes. Q dealing with normothermia; correct? A. Uh-huh. Q. Yes?
7 8 9 10 11 12	ever been a study which the result was not favorable to the corporate sponsor? A. Probably. Q. Okay. And But you don't know one way or the other? A. Correct. Q. Okay. So I don't want you to guess. So	7 8 9 10 11 12 13	 Q. Okay. I assume you're familiar with host defense A. Yes. Q dealing with normothermia; correct? A. Uh-huh. Q. Yes? A. Yes.
7 8 9 10 11 12 13	ever been a study which the result was not favorable to the corporate sponsor? A. Probably. Q. Okay. And But you don't know one way or the other? A. Correct. Q. Okay. So I don't want you to guess. So you	7 8 9 10 11 12 13 14	 Q. Okay. I assume you're familiar with host defense A. Yes. Q dealing with normothermia; correct? A. Uh-huh. Q. Yes? A. Yes. Q. All right. Do you have
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7 8 9 10 11 12 13 14 15 16 17 18 19 20	ever been a study which the result was not favorable to the corporate sponsor? A. Probably. Q. Okay. And But you don't know one way or the other? A. Correct. Q. Okay. So I don't want you to guess. So you A. Yeah. Q. Sitting here today, you don't know. A. Yeah. Q. Okay. Have you reviewed any documents in preparation of today's deposition? A. No.	7 8 9 10 11 12 13 14 15 16 17 18 19 20	 Q. Okay. I assume you're familiar with host defense A. Yes. Q dealing with normothermia; correct? A. Uh-huh. Q. Yes? A. Yes. Q. All right. Do you have With respect to periprosthetic joint infections, do you understand that the standard of care is to remove and replace the joint? Do you understand that? Are you aware of that? A. Yes, I am. Q. Okay. And is that based on doing anesthesia
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	ever been a study which the result was not favorable to the corporate sponsor? A. Probably. Q. Okay. And But you don't know one way or the other? A. Correct. Q. Okay. So I don't want you to guess. So you A. Yeah. Q. Sitting here today, you don't know. A. Yeah. Q. Okay. Have you reviewed any documents in preparation of today's deposition? A. No. Q. Have you had any discussions with anyone	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 Q. Okay. I assume you're familiar with host defense A. Yes. Q dealing with normothermia; correct? A. Uh-huh. Q. Yes? A. Yes. Q. All right. Do you have With respect to periprosthetic joint infections, do you understand that the standard of care is to remove and replace the joint? Do you understand that? Are you aware of that? A. Yes, I am. Q. Okay. And is that based on doing anesthesia for revision surgeries?
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	ever been a study which the result was not favorable to the corporate sponsor? A. Probably. Q. Okay. And But you don't know one way or the other? A. Correct. Q. Okay. So I don't want you to guess. So you A. Yeah. Q. Sitting here today, you don't know. A. Yeah. Q. Okay. Have you reviewed any documents in preparation of today's deposition? A. No. Q. Have you had any discussions with anyone besides your attorney with regard to today's	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 Q. Okay. I assume you're familiar with host defense A. Yes. Q dealing with normothermia; correct? A. Uh-huh. Q. Yes? A. Yes. Q. All right. Do you have With respect to periprosthetic joint infections, do you understand that the standard of care is to remove and replace the joint? Do you understand that? Are you aware of that? A. Yes, I am. Q. Okay. And is that based on doing anesthesia for revision surgeries? A. Yes.

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	Page 49		Page 51
1 4	-	1	
	hat has attached itself to an inanimate object such is a as a a joint, an artificial joint?	$\begin{array}{c c} 1 \\ 2 \end{array}$	Q. Are there different types of operating rooms in the Cleveland Clinic?
3	MR. GORDON: Object to the form of the	3	MR. GORDON: Object to the form of the
	question.	4	question.
5	MS. DIFRANCO: Go ahead if you if you	5	MS. DIFRANCO: What do you mean by
	mow.	6	"different?"
7	A. I would say yes.	7	Q. Like is there an ultraclean operating room
8	Q. Because there's lack of blood flow to the	8	that's used for orthopedic procedures as compared to
	o the joint; correct?	9	other operating rooms?
10	A. Correct.	10	A. It's not called ultraclean, but there might
11	Q. Okay. You're familiar with that; correct?	11	be differences in airflow, yes.
12	A. Yes, I am.	12	Q. Okay. Are are the orthopedic procedures
13	Q. Okay. And sitting here today, you have done	13	that are, you know, total hip or total knee done in
-	no studies with respect to normothermia and the	14	certain operating rooms as compared to other
	ncidence of periprosthetic joint infection.	15	surgeries?
16	A. That's correct.	16	A. Yes, they are.
17	Q. Okay. And sitting here today, you're aware	17	Q. Where are they where are they performed
	of no studies conducted by you yourself or anyone in	18	at?
	he field with respect to normothermia and incidence	19	A. Oh, they are performed here in the E
	of infection in orthopedic surgeries.	20	Building and in ORs that have a laminar airflow
21	A. I don't know studies about that, yes.	21	technique.
22	Q. Okay. Well you you're an expert in the	22	Q. Is it laminar or unidirectional, do you
	ield of normothermia; correct?	23	know?
24	A. Yes.	24	A. Oh, God. I don't know.
25	Q. And many of the studies are conducted	25	Q. That's fair enough.
	Page 50		Page 52
1 p	robably like through Outcomes Research with	1	A. Yeah.
2 re	espect to normothermia.	2	Q. Okay.
3	A. That is correct.	3	A. I don't know.
4		ı ~	
	Q. Okay. And if a study comes out that is a	4	Q. Do you know why they're performed in those
5 s i	ignificant study, you you you keep yourself	4 5	Q. Do you know why they're performed in those operating rooms as compared to other operating rooms?
5 si 6 aj	ignificant study, you you you keep yourself pprised of of the the the research	4	Q. Do you know why they're performed in those operating rooms as compared to other operating rooms?A. I actually don't, no.
5 si 6 aj 7 ti	ignificant study, you you you keep yourself pprised of of the the the the research nat's being done and the publications in the field of	4 5 6 7	 Q. Do you know why they're performed in those operating rooms as compared to other operating rooms? A. I actually don't, no. Q. Okay. So currently you consult for 3M and
5 si 6 aj 7 tl	ignificant study, you you you keep yourself pprised of of the the the the research nat's being done and the publications in the field of ormothermia; correct?	4 5 6	Q. Do you know why they're performed in those operating rooms as compared to other operating rooms?A. I actually don't, no.
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5 si 6 a 7 tl 8 n 9	ignificant study, you you you keep yourself pprised of of the the the research nat's being done and the publications in the field of ormothermia; correct? A. Mostly, yes. Q. Are you also aware that the number of CFUs	4 5 6 7 8 9	 Q. Do you know why they're performed in those operating rooms as compared to other operating rooms? A. I actually don't, no. Q. Okay. So currently you consult for 3M and Mercury Biomed. A. Yes. Q. What what percentage of your income is
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5 si 6 aq 7 tl 8 n 9 10 11 rd 12 m 13 14 q 15 16 17 18 19 20 fc	ignificant study, you you you keep yourself pprised of of the the the research nat's being done and the publications in the field of ormothermia; correct? A. Mostly, yes. Q. Are you also aware that the number of CFUs equired to cause a periprosthetic joint infection is nuch less than is required to cause a wound infection? MR. GORDON: Objection to the form of the uestion. A. I that I have no Q. Is that outside your expertise? A. That is outside of my expertise, yes. Q. That's fine. Dealing with doing anesthesia services or for patients that undergo total knee or total	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. Do you know why they're performed in those operating rooms as compared to other operating rooms? A. I actually don't, no. Q. Okay. So currently you consult for 3M and Mercury Biomed. A. Yes. Q. What what percentage of your income is derived from consulting for 3M? A. Barely anything. Q. Well how much do you get paid by 3M per hour for consulting? A. You know, I don't know the per-hour pay. Q. You receive checks from 3M? A. I do when I give a talk for them. Q. Okay. And you And I understand they'll pay your costs, to reimburse your costs; correct?
5 si 6 a 7 tf 8 n 9 10 11 rc 12 m 13 14 q 15 16 17 18 19 20 fc 21 h	ignificant study, you you you keep yourself pprised of of the the the research nat's being done and the publications in the field of ormothermia; correct? A. Mostly, yes. Q. Are you also aware that the number of CFUs equired to cause a periprosthetic joint infection is nuch less than is required to cause a wound infection? MR. GORDON: Objection to the form of the uestion. A. I that I have no Q. Is that outside your expertise? A. That is outside of my expertise, yes. Q. That's fine. Dealing with doing anesthesia services or for patients that undergo total knee or total ip arthroplasty and and, you know, dealing with	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Do you know why they're performed in those operating rooms as compared to other operating rooms? A. I actually don't, no. Q. Okay. So currently you consult for 3M and Mercury Biomed. A. Yes. Q. What what percentage of your income is derived from consulting for 3M? A. Barely anything. Q. Well how much do you get paid by 3M per hour for consulting? A. You know, I don't know the per-hour pay. Q. You receive checks from 3M? A. I do when I give a talk for them. Q. Okay. And you And I understand they'll pay your costs, to reimburse your costs; correct? A. Yes.
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5 si 6 a 7 tt 8 n 9 10 11 rr 12 m 13 14 q 15 16 17 18 19 20 fc 21 h 22 tt 23 p	ignificant study, you you you keep yourself pprised of of the the the research nat's being done and the publications in the field of ormothermia; correct? A. Mostly, yes. Q. Are you also aware that the number of CFUs equired to cause a periprosthetic joint infection is nuch less than is required to cause a wound infection? MR. GORDON: Objection to the form of the uestion. A. I that I have no Q. Is that outside your expertise? A. That is outside of my expertise, yes. Q. That's fine. Dealing with doing anesthesia services or for patients that undergo total knee or total ip arthroplasty and and, you know, dealing with ne with the orthopedic surgeon, are you aware that atients that undergo those procedures are more	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. Do you know why they're performed in those operating rooms as compared to other operating rooms? A. I actually don't, no. Q. Okay. So currently you consult for 3M and Mercury Biomed. A. Yes. Q. What what percentage of your income is derived from consulting for 3M? A. Barely anything. Q. Well how much do you get paid by 3M per hour for consulting? A. You know, I don't know the per-hour pay. Q. You receive checks from 3M? A. I do when I give a talk for them. Q. Okay. And you And I understand they'll pay your costs, to reimburse your costs; correct? A. Yes. Q. They also give you money for for a day of your time or per hour; correct?
5 si 6 a 7 tt 8 n 9 10 11 rr 12 m 13 14 q 15 16 17 18 19 20 fc 21 h 22 tt 23 p	ignificant study, you you you keep yourself pprised of of the the the research nat's being done and the publications in the field of ormothermia; correct? A. Mostly, yes. Q. Are you also aware that the number of CFUs equired to cause a periprosthetic joint infection is much less than is required to cause a wound infection? MR. GORDON: Objection to the form of the uestion. A. I that I have no Q. Is that outside your expertise? A. That is outside of my expertise, yes. Q. That's fine. Dealing with doing anesthesia services or for patients that undergo total knee or total ip arthroplasty and and, you know, dealing with ne with the orthopedic surgeon, are you aware that	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Do you know why they're performed in those operating rooms as compared to other operating rooms? A. I actually don't, no. Q. Okay. So currently you consult for 3M and Mercury Biomed. A. Yes. Q. What what percentage of your income is derived from consulting for 3M? A. Barely anything. Q. Well how much do you get paid by 3M per hour for consulting? A. You know, I don't know the per-hour pay. Q. You receive checks from 3M? A. I do when I give a talk for them. Q. Okay. And you And I understand they'll pay your costs, to reimburse your costs; correct? A. Yes. Q. They also give you money for for a day of

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	Page 53		Page 55
1	A. It could be something else.	1	at the association between intraoperative hypothermia
2	Q. Is it around \$3,000 a day?	2	and post-op infections, very much like the one you
3	A. Could be.	3	mentioned before about blood loss.
4	Q. Okay. Well around that number, give your	4	Q. Okay. And what type of infections?
5	take?	5	A. Those are those are anything from
6	A. Yeah.	6	superficial to deep infections
7	Q. Okay. And that's for when you give talks or	7	Q. Okay.
8	you have or when you go for meetings with the	8	A according to CDC criteria.
9	advise advisory board; correct?	9	Q. Okay. And this is
10	A. Exactly.	10	Are you looking at just here in the
11	Q. Okay. When is the last time you had an	11	Cleveland Clinic?
12	advisory board meeting with 3M?	12	A. Yes.
13	A. I don't know exactly, but it's I think	13	Q. Okay. So you're going through the Cleveland
14	it's more than two years ago.	14	Clinic database.
15	Q. Okay. What about discussions with 3M over	15	A. Absolutely.
16	the phone that's not related to research?	16	Q. Okay. And 3M is funding that?
17	A. Last one, half a year ago.	17	A. Yes.
18	Q. Okay.	18	Q. And when you say "intraoperative
19	A. October, September.	19	hypothermia," I know there's been a big discussion of
20	Q. And it's my understanding that the money	20	what actually is hypothermia, what degree. In your
21	that you obtain from your consulting services, giving	21	opinion, what is the degree
22	talks, is paid to you and not to the Cleveland Clinic;	22	What degree Celsius is considered
23	correct?	23	hypothermia, below what number?
24	A. That is correct.	24	A. I would say everything below the normal core
25	Q. Before I leave your CV, I have a quick	25	temperature.
	Page 54		Page 56
1	question. Maybe this will remind you of your current	1	Q. Which is?
2	question. Maybe this will remind you of your current research for 3M.	2	Q. Which is?A. Whatever you come in with; 36.7 maybe for
2 3	question. Maybe this will remind you of your current research for 3M. (Exhibit 239 was marked for	2	Q. Which is? A. Whatever you come in with; 36.7 maybe for you, 36.8 for me, whichever is your preoperative core
2 3 4	question. Maybe this will remind you of your current research for 3M. (Exhibit 239 was marked for identification.)	2 3 4	Q. Which is? A. Whatever you come in with; 36.7 maybe for you, 36.8 for me, whichever is your preoperative core temperature.
2 3	question. Maybe this will remind you of your current research for 3M. (Exhibit 239 was marked for identification.) BY MR. ASSAAD:	2	 Q. Which is? A. Whatever you come in with; 36.7 maybe for you, 36.8 for me, whichever is your preoperative core temperature. Q. Okay. Fair enough. So anything below the
2 3 4 5 6	question. Maybe this will remind you of your current research for 3M. (Exhibit 239 was marked for identification.) BY MR. ASSAAD: Q. What's been marked as Exhibit 239 is an	2 3 4 5 6	Q. Which is? A. Whatever you come in with; 36.7 maybe for you, 36.8 for me, whichever is your preoperative core temperature. Q. Okay. Fair enough. So anything below the core temperature. But when you when when you
2 3 4 5 6 7	question. Maybe this will remind you of your current research for 3M. (Exhibit 239 was marked for identification.) BY MR. ASSAAD: Q. What's been marked as Exhibit 239 is an e-mail from Daniel Sessler to Mark Morken, and you are	2 3 4 5 6 7	 Q. Which is? A. Whatever you come in with; 36.7 maybe for you, 36.8 for me, whichever is your preoperative core temperature. Q. Okay. Fair enough. So anything below the core temperature. But when you when when you Let me ask it this way. This is more
2 3 4 5 6	question. Maybe this will remind you of your current research for 3M. (Exhibit 239 was marked for identification.) BY MR. ASSAAD: Q. What's been marked as Exhibit 239 is an e-mail from Daniel Sessler to Mark Morken, and you are also copied on the e-mail along with Michelle Stevens,	2 3 4 5 6	 Q. Which is? A. Whatever you come in with; 36.7 maybe for you, 36.8 for me, whichever is your preoperative core temperature. Q. Okay. Fair enough. So anything below the core temperature. But when you when when you Let me ask it this way. This is more education for me. Is is that why lately you've
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2 3 4 5 6 7 8 9	question. Maybe this will remind you of your current research for 3M. (Exhibit 239 was marked for identification.) BY MR. ASSAAD: Q. What's been marked as Exhibit 239 is an e-mail from Daniel Sessler to Mark Morken, and you are also copied on the e-mail along with Michelle Stevens, and the subject is "Protocol drafts for Hypothermia-MINS retrospective analysis & Intraoperative Core Temperature and Infectious	2 3 4 5 6 7 8	Q. Which is? A. Whatever you come in with; 36.7 maybe for you, 36.8 for me, whichever is your preoperative core temperature. Q. Okay. Fair enough. So anything below the core temperature. But when you when when you Let me ask it this way. This is more education for me. Is is that why lately you've been more going with this like in research, more of the delta, the change, A. Yes, absolutely.
2 3 4 5 6 7 8 9	question. Maybe this will remind you of your current research for 3M. (Exhibit 239 was marked for identification.) BY MR. ASSAAD: Q. What's been marked as Exhibit 239 is an e-mail from Daniel Sessler to Mark Morken, and you are also copied on the e-mail along with Michelle Stevens, and the subject is "Protocol drafts for Hypothermia-MINS retrospective analysis &	2 3 4 5 6 7 8 9	Q. Which is? A. Whatever you come in with; 36.7 maybe for you, 36.8 for me, whichever is your preoperative core temperature. Q. Okay. Fair enough. So anything below the core temperature. But when you when when you Let me ask it this way. This is more education for me. Is is that why lately you've been more going with this like in research, more of the delta, the change,
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2 3 4 5 6 7 8 9 10 11 12 13	question. Maybe this will remind you of your current research for 3M. (Exhibit 239 was marked for identification.) BY MR. ASSAAD: Q. What's been marked as Exhibit 239 is an e-mail from Daniel Sessler to Mark Morken, and you are also copied on the e-mail along with Michelle Stevens, and the subject is "Protocol drafts for Hypothermia-MINS retrospective analysis & Intraoperative Core Temperature and Infectious Complications after Colorectal Surgery." A. Uh-huh, yes.	2 3 4 5 6 7 8 9 10 11 12 13	Q. Which is? A. Whatever you come in with; 36.7 maybe for you, 36.8 for me, whichever is your preoperative core temperature. Q. Okay. Fair enough. So anything below the core temperature, But when you when when you Let me ask it this way. This is more education for me. Is is that why lately you've been more going with this like in research, more of the delta, the change, A. Yes, absolutely. Q as compared to a hard number? Is that a yes?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	question. Maybe this will remind you of your current research for 3M. (Exhibit 239 was marked for identification.) BY MR. ASSAAD: Q. What's been marked as Exhibit 239 is an e-mail from Daniel Sessler to Mark Morken, and you are also copied on the e-mail along with Michelle Stevens, and the subject is "Protocol drafts for Hypothermia-MINS retrospective analysis & Intraoperative Core Temperature and Infectious Complications after Colorectal Surgery." A. Uh-huh, yes. Q. And this was dated March 18th, 2016. A. Yeah. Q. The second one, "Intraoperative Core	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. Which is? A. Whatever you come in with; 36.7 maybe for you, 36.8 for me, whichever is your preoperative core temperature. Q. Okay. Fair enough. So anything below the core temperature. But when you when when you Let me ask it this way. This is more education for me. Is is that why lately you've been more going with this like in research, more of the delta, the change, A. Yes, absolutely. Q as compared to a hard number? Is that a yes? A. Yes. Q. Okay. But in the 2015 study you used 37 degrees as the baseline and the delta C of one would
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	question. Maybe this will remind you of your current research for 3M. (Exhibit 239 was marked for identification.) BY MR. ASSAAD: Q. What's been marked as Exhibit 239 is an e-mail from Daniel Sessler to Mark Morken, and you are also copied on the e-mail along with Michelle Stevens, and the subject is "Protocol drafts for Hypothermia-MINS retrospective analysis & Intraoperative Core Temperature and Infectious Complications after Colorectal Surgery." A. Uh-huh, yes. Q. And this was dated March 18th, 2016. A. Yeah. Q. The second one, "Intraoperative Core Temperature and Infectious Complications after	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. Which is? A. Whatever you come in with; 36.7 maybe for you, 36.8 for me, whichever is your preoperative core temperature. Q. Okay. Fair enough. So anything below the core temperature. But when you when when you Let me ask it this way. This is more education for me. Is is that why lately you've been more going with this like in research, more of the delta, the change, A. Yes, absolutely. Q as compared to a hard number? Is that a yes? A. Yes. Q. Okay. But in the 2015 study you used 37 degrees as the baseline and the delta C of one would be 36, and below that would be considered hypothermia;
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	question. Maybe this will remind you of your current research for 3M. (Exhibit 239 was marked for identification.) BY MR. ASSAAD: Q. What's been marked as Exhibit 239 is an e-mail from Daniel Sessler to Mark Morken, and you are also copied on the e-mail along with Michelle Stevens, and the subject is "Protocol drafts for Hypothermia-MINS retrospective analysis & Intraoperative Core Temperature and Infectious Complications after Colorectal Surgery." A. Uh-huh, yes. Q. And this was dated March 18th, 2016. A. Yeah. Q. The second one, "Intraoperative Core Temperature and Infectious Complications after Colorectal Surgery," is that the is that the Protect study? A. No, it is not. It's a retrospective analysis. Q. Okay. Is that ongoing right now?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Which is? A. Whatever you come in with; 36.7 maybe for you, 36.8 for me, whichever is your preoperative core temperature. Q. Okay. Fair enough. So anything below the core temperature. But when you when when you Let me ask it this way. This is more education for me. Is is that why lately you've been more going with this like in research, more of the delta, the change, A. Yes, absolutely. Q as compared to a hard number? Is that a yes? A. Yes. Q. Okay. But in the 2015 study you used 37 degrees as the baseline and the delta C of one would be 36, and below that would be considered hypothermia; correct? A. Yes. Q. So you used 36 as your level A. As a cutoff. Q. Okay. So what what
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	question. Maybe this will remind you of your current research for 3M. (Exhibit 239 was marked for identification.) BY MR. ASSAAD: Q. What's been marked as Exhibit 239 is an e-mail from Daniel Sessler to Mark Morken, and you are also copied on the e-mail along with Michelle Stevens, and the subject is "Protocol drafts for Hypothermia-MINS retrospective analysis & Intraoperative Core Temperature and Infectious Complications after Colorectal Surgery." A. Uh-huh, yes. Q. And this was dated March 18th, 2016. A. Yeah. Q. The second one, "Intraoperative Core Temperature and Infectious Complications after Colorectal Surgery," is that the is that the Protect study? A. No, it is not. It's a retrospective analysis.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Which is? A. Whatever you come in with; 36.7 maybe for you, 36.8 for me, whichever is your preoperative core temperature. Q. Okay. Fair enough. So anything below the core temperature. But when you when when you Let me ask it this way. This is more education for me. Is is that why lately you've been more going with this like in research, more of the delta, the change, A. Yes, absolutely. Q as compared to a hard number? Is that a yes? A. Yes. Q. Okay. But in the 2015 study you used 37 degrees as the baseline and the delta C of one would be 36, and below that would be considered hypothermia; correct? A. Yes. Q. So you used 36 as your level A. As a cutoff.

14 (Pages 53 to 56)

	Page 57		Page 59
1	you what's your opinion to use?	1	A. Roughly, yes.
2	A. We still use 36.	2	Q. You understand that it takes air in, heats
3	Q. Okay.	3	up the air, goes through a hose into a blanket, and
4	A. Although arbitrary.	4	blows hot air through tiny holes over the patient.
5	Q. And some people use 35.5,	5	A. Yes.
6	A. No.	6	Q. Are you aware that the air that's being
7	Q or is it 36.5?	7	drawn from the Bair Hugger unit is the intake is
8	A. I think internationally most people use	8	from the bottom of the unit that's on the floor?
9	36.5.	9	MR. GORDON: Object to the form of the
10	Q. Okay. And when you consider mild hyp	10	question.
11	hypothermia, what's considered mild hypothermia,	11	MS. DIFRANCO: Go ahead if you if you
12		12	
	What what degree level before 36?		know.
13	A. I would say 36 35.5.	13	A. I actually don't.
14	Q. So 35.5 to 36 is mild hypothermia?	14	Q. Have you ever studied the Bair Hugger or
15	A. Uh-huh.	15	looked at it?
16	THE REPORTER: Your answer?	16	A. Yeah.
17	Q. Yes?	17	Q. Have you ever felt where the air is coming
18	A. Yes.	18	in and coming out of?
19	Q. And then anything below 35.5, you consider	19	A. No.
20	it hypothermia.	20	What's coming out, yes.
21	A. Yes.	21	Q. Okay. So sitting here today, you're not
22	Q. And my understanding is at 34.5, the body	22	aware that for the model
23	vasoconstricts and usually remains at 34.5 degrees;	23	Do you know what the model 750 is, the blue
24	correct?	24	Bair Hugger?
25	A. Simply said, yes.	25	A. Yes.
	Page 58		Page 60
1	Q. What what's the more complex way of	1	Q. Okay. And actually, you've done testing on
2	saying it then?	2	the model 750 in some of your research; correct?
3	A. 34.5 isn't exactly. It it it depends	3	You used the model 750 as your forced-air
4	on the patient's physiology and type and dose of	4	warming device you you've used in research.
5	anesthesia at which the patient vasoconstricts. But	5	A. I don't know which model we used.
6	you are correct, 35.5 is a round, I think	6	Q. Okay. Fair enough. But you are familiar
7	Q. An arbitrary number that's rounded such as	7	with the 750 or the the model that's blue.
8 .	36	8	A. I believe so, yes.
9	A. Yeah.	9	Q. Okay. And are you aware that the intake
10	Q degrees for	10	manifold of air is on the bottom of that unit?
11	A. It's not quite as arbitrary, no.	11	A. No.
12	Q. But my point is, I mean 36 is not an exact	12	Q. Okay. Would that cause you any concern?
13	number for	13	A. No.
14		i .	
	A. Huh-uh.	14	Q. Why not?
15	Q. It's a number that people use; correct?	`15	A. Which difference makes does it make
16	A. Yes.	16	whether it's at the bottom or the top?
17	Q. And 34.5 is the number they use when people	17	Q. Is is the is the operating room floor
18	say patients will vasoconstrict.	18	clean?
19	A. Exactly. Yes.	19	A. No.
	Q. Now are you familiar with the way the Bair	20	Q. Okay. Are you concerned that the air that
20	Hugger works	21	is drawn into the Bair Hugger is is drawing air
20 21		22	from the operating room floor?
	MR. GORDON: I object to the form of the	,	
21	MR. GORDON: I object to the form of the question.	23	A. No.
21 22	question.	i	A. No.
21 22 23		23	- -

15 (Pages 57 to 60)

	Page 61		Page 63
1	and I'm I doubt that the air changes much within	1	Augustine's claims that blowing air is risky. That's
2	whatever a size of the device would be. I mean	2	your testimony today.
3	Q. You don't think the operating floor is not	. 3	A. No.
4	sterile?	4	Q. What is your testimony today?
5	A. I know it's not sterile.	5	A. I've been in advisory committees where it
6	Q. Okay. But the sterile site is is	6	has been discussed, but that wasn't your previous
7	considered sterile, correct, where the operating	7	question.
- 8	procedure is being performed?	8	Q. So you've been in advisory meetings
. 9	MR. GORDON: Object to the form of the	9	A. Yes.
10	question.	10	Q where it's been discussed. And have you
11	A. Yeah. Can you	11	had any input on on those discussions?
12	Q. Okay. Are you sitting here today and saying	12	A. No.
13	to me that strike that.	13	(Discussion off the stenographic record.)
14	Are there any parts of the operating room	14	BY MR. ASSAAD:
15	that are considered sterile, such as the sterile	15	Q. So have you investigated or studied or done
16	field?	16	any research on whether the Bair Hugger unit itself
17	A. Yes.	17.	can become internally contaminated with microbes?
18	Q. Okay. And you agree with me that the goal	18	A. No.
19	of the operating personnel is to keep the sterile	19	Q. Would that be, if it did become
20	field as sterile as possible.	20	If it could become contaminated with
21	A. Yes.	21	microbes, would that be of any concern to you as an
22	Q. Okay. As a result, you surgeons try to	22	anesthesiologist using the device in the operating
23	keep their hands above the operating room table at all	23	room?
24	times; correct?	24	A. I believe I actually believe not.
25	A. I assume.	25	Q. Why not?
4	Page 62		Page 64
1	Q. Okay. You don't know one way or the other?	1 2	A. It's because I mean there are so there
2	A. No.	3	are so many I mean I mean if you're in an operating room, there
3 4	Q. I don't want you to assume. If you don't know, just say you don't know.	4	are so many people in the room, there's so much
5	A. No, not not the way you asked. Yes. No.	5	airflow going on with or without a device that might
- 6	Q. You don't know one way or the other. Okay.	6	have some bacteria in there that I would not consider
7	A. Yeah.	7	it clinically relevant.
8	Q. So sitting here today as an	8	Q. Is there any other device that you're aware
_	anesthesiologist, do you have any concern of whether		of that blows air that can be contaminated onto the
9 10	or not any contaminants can get inside the Bair Hugger	10	patient in the operating room?
11	unit?	11	A. A warming device?
12		12	Q. Any device.
13	A. I actually don't.Q. Have you ever thought about it before?	13	A. I don't know.
14	A. Very little.	14	Q. How many surgeries have you sat in on?
15	Q. Have you ever been in any discussions with	15	A. How many?
15. 16	3M regarding Dr. Augustine's claims about the	16	Q. How many surgeries have you done in the past
	contamination of of these units?	17	where you're the anesthesiologist?
		18	A. Oh, many thousands.
17	A I have not		Q. Thousands, correct? And you have the the
17 18	A. I have not. O. Okay. Have you ever been in any	19	
17 18 19	Q. Okay. Have you ever been in any	19	
17 18 19 20	Q. Okay. Have you ever been in any conversations with 3M regarding Dr. Augustine's claim	20	clean air coming from the top of the of the
17 18 19 20 21	Q. Okay. Have you ever been in any conversations with 3M regarding Dr. Augustine's claim that blowing air is risky?	20 21	clean air coming from the top of the of the operating room; correct?
17 18 19 20 21 22	Q. Okay. Have you ever been in any conversations with 3M regarding Dr. Augustine's claim that blowing air is risky? A. I I personally have not.	20 21 22	clean air coming from the top of the of the operating room; correct? A. Yes.
17 18 19 20 21 22 23	 Q. Okay. Have you ever been in any conversations with 3M regarding Dr. Augustine's claim that blowing air is risky? A. I I personally have not. Q. So you, sitting here today, you personally 	20 21 22 23	clean air coming from the top of the of the operating room; correct? A. Yes. Q. Okay. Are you aware of any other device
17 18 19 20 21 22	Q. Okay. Have you ever been in any conversations with 3M regarding Dr. Augustine's claim that blowing air is risky? A. I I personally have not.	20 21 22	clean air coming from the top of the of the operating room; correct? A. Yes.

16 (Pages 61 to 64)

•	Page 65		Page 67
1	A. No.	1	Yes?
2	Q. Okay. So if the air is contaminated with	2	A. Yes.
3	microbes, you would you think that would be a good	3	Q. And it cultured positive for Acinetobacter?
4 .	thing or a safe thing for the patients?	4	A. Yes.
5	MR. GORDON: Object to the form of the	5	Q. Out of curiosity, do you know whether or not
6	question.	6	Cleveland Clinic cultures or gets random cultures
7	A. It would	. 7	of their Bair Hugger units to see if there are any
8	MS. DIFRANCO: Go ahead. Yeah, you can	8	microbes on them?
9	answer.	9	A. I don't know.
10	A. I think it would not, but I'm not convinced	10	Q. Okay. And and the title of this
11	it is.	11	The subject matter of this of this e-mail
12	Q. You don't think it would blow contaminants	12	chain is called or exchange is "Contaminated?"
13	onto the patient?	13	from where Mathieu, Rick, sends it or forwards it to
14	A. I don't know whether it's as im	14	someone at 3M. Do you see that?
15	Actually, I don't know. I don't know.	1.5 ⁻	A. Yes.
16	Q. So as an anesthesiologist, if if if	16	Q. Okay. Were you aware that the Bair Hugger
17	you found out or became aware that the the Bair	17	blowers can become contaminated
18	Hugger device being used in your surgeries has a	18	MR. GORDON: Object to the form of the
19	potential of having microbes in it, or contaminants,	19	question.
20	that would be of no concern to you.	20	Q prior to this e-mail?
21	MS. DIFRANCO: Object. You've asked and	21	MR. GORDON: Objection to the form form
22	answered asked her three times already.	22	of the question, also lack of foundation.
23	MR. ASSAAD: Well she's been back and forth.	23	MS. DIFRANCO: Go ahead.
24	I want to get a final answer.	24	A. I
25	MR. GORDON: Move to strike counsel's	25	Yeah.
	Page 66		Page 68
1	comments.	1	Q. You were aware prior to this e-mail that
2	A. I have no concerns in regards to that	2	Bair Hugger units can become contaminated?
3	question.	3	A. Prior to you showing me that.
4	Q. Fair enough.	4	Q. Yes. Prior to today
5	MR. ASSAAD: We can take a break.	5	A. Yes.
6	THE REPORTER: Off the record, please.	6	Q were you aware that Bair Huggers can
7	(Recess taken.)	7	become contaminated?
8	BY MR. ASSAAD:	8	A. I have heard about it, yes.
9	Q. I'd like to show you what's been marked as	9	Q. How did you hear about it?
10	Exhibit 66.	10	A. Oh, I don't know.
11	(Discussion off the stenographic record.)	11	Q. Has that caused you any concern with respect
12	Q. Exhibit 66 is an e-mail from Al Van Duren to	12	to the use of the Bair Hugger unit?
			. 37
13	Mark Scott, Gary Hansen and Dave Westlin entitled	13	A. No.
14	or dated February 20, 2009. Just please review this	14	Q. All right. Do you see on the top of the
14 15	or dated February 20, 2009. Just please review this e-mail front and back.	14 15	Q. All right. Do you see on the top of the e-mail, the last e-mail, it says from Al Van Duren?
14 15 16	or dated February 20, 2009. Just please review this e-mail front and back. A. Oh, I start in the back?	14 15 16	Q. All right. Do you see on the top of the e-mail, the last e-mail, it says from Al Van Duren?A. Uh-huh.
14 15 16 17	or dated February 20, 2009. Just please review this e-mail front and back. A. Oh, I start in the back? Uh-huh.	14 15 16 17	 Q. All right. Do you see on the top of the e-mail, the last e-mail, it says from Al Van Duren? A. Uh-huh. Q. And you you know who Al Van Duren is;
14 15 16 17 18	or dated February 20, 2009. Just please review this e-mail front and back. A. Oh, I start in the back? Uh-huh. Q. Okay. If you look	14 15 16 17	 Q. All right. Do you see on the top of the e-mail, the last e-mail, it says from Al Van Duren? A. Uh-huh. Q. And you you know who Al Van Duren is; correct?
14 15 16 17 18 19	or dated February 20, 2009. Just please review this e-mail front and back. A. Oh, I start in the back? Uh-huh. Q. Okay. If you look If you go to the back, it seems back on	14 15 16 17 18 19	 Q. All right. Do you see on the top of the e-mail, the last e-mail, it says from Al Van Duren? A. Uh-huh. Q. And you you know who Al Van Duren is; correct? A. Yes, I do.
14 15 16 17 18 19	or dated February 20, 2009. Just please review this e-mail front and back. A. Oh, I start in the back? Uh-huh. Q. Okay. If you look If you go to the back, it seems back on February 20th, 2009, the Director of Materials	14 15 16 17 18 19 20	 Q. All right. Do you see on the top of the e-mail, the last e-mail, it says from Al Van Duren? A. Uh-huh. Q. And you you know who Al Van Duren is; correct? A. Yes, I do. Q. Okay. It says, "Remove and discard the
14 15 16 17 18 19 20	or dated February 20, 2009. Just please review this e-mail front and back. A. Oh, I start in the back? Uh-huh. Q. Okay. If you look If you go to the back, it seems back on February 20th, 2009, the Director of Materials Management at Memorial Hermann Hospital in Texas took	14 15 16 17 18 19 20 21	 Q. All right. Do you see on the top of the e-mail, the last e-mail, it says from Al Van Duren? A. Uh-huh. Q. And you you know who Al Van Duren is; correct? A. Yes, I do. Q. Okay. It says, "Remove and discard the filter (in the biohazardous waste)."
14 15 16 17 18 19 20 21	or dated February 20, 2009. Just please review this e-mail front and back. A. Oh, I start in the back? Uh-huh. Q. Okay. If you look If you go to the back, it seems back on February 20th, 2009, the Director of Materials Management at Memorial Hermann Hospital in Texas took a culture of a model 750 unit Bair Hugger. Do you see	14 15 16 17 18 19 20 21 22	 Q. All right. Do you see on the top of the e-mail, the last e-mail, it says from Al Van Duren? A. Uh-huh. Q. And you you know who Al Van Duren is; correct? A. Yes, I do. Q. Okay. It says, "Remove and discard the filter (in the biohazardous waste)." A. Yes, I see.
14 15 16 17 18 19 20 21 22 23	or dated February 20, 2009. Just please review this e-mail front and back. A. Oh, I start in the back? Uh-huh. Q. Okay. If you look If you go to the back, it seems back on February 20th, 2009, the Director of Materials Management at Memorial Hermann Hospital in Texas took a culture of a model 750 unit Bair Hugger. Do you see that	14 15 16 17 18 19 20 21 22 23	 Q. All right. Do you see on the top of the e-mail, the last e-mail, it says from Al Van Duren? A. Uh-huh. Q. And you you know who Al Van Duren is; correct? A. Yes, I do. Q. Okay. It says, "Remove and discard the filter (in the biohazardous waste)." A. Yes, I see. Q. Okay. Do you know do you know why you'd
14 15 16 17 18 19 20 21	or dated February 20, 2009. Just please review this e-mail front and back. A. Oh, I start in the back? Uh-huh. Q. Okay. If you look If you go to the back, it seems back on February 20th, 2009, the Director of Materials Management at Memorial Hermann Hospital in Texas took a culture of a model 750 unit Bair Hugger. Do you see	14 15 16 17 18 19 20 21 22	 Q. All right. Do you see on the top of the e-mail, the last e-mail, it says from Al Van Duren? A. Uh-huh. Q. And you you know who Al Van Duren is; correct? A. Yes, I do. Q. Okay. It says, "Remove and discard the filter (in the biohazardous waste)." A. Yes, I see.

17 (Pages 65 to 68)

	Page 69		Page 71
1	MR. GORDON: Object to the form of the	1	Q. You don't want to create a device or do
2	question, and also lack of foundation.	2	anything that may put the patient at harm.
3	A. I I don't know why. I can only make	3.	MR. GORDON: Object to the form of the
4	assumptions.	4	question.
5	Q. Okay. Has 3M ever mentioned or indicated to	5	A. You have never proven to me that a patient
6	you that the Bair Hugger units can become	6	is at harm.
7	contaminated?	7	Q. I didn't say prove. I say you yourself
8	A. I don't recall.	8	would never want to advise a company to create a
9	Q. Now in the e-mail it says, "Remove and	9	product or manufacture a product that may put a
10	discard the filter (in the biohazardous waste).	10	patient at harm.
1.1	"Clean the filter retainer and the outside	11	MR. GORDON: Object to the form of the
12	of the unit (including the hose) with full spectrum	12	question.
13	(quaternary ammonium salt) antiseptic wipe or spray.	13	MS. DIFRANCO: Go ahead.
14	"Wipe off all surfaces and install a new	14	A. Yes, you're correct.
15	filter."	15	Q. Okay. And you yourself as an orthopedic
16	Did I read do you see where I read that	16	surgeon or as an anesthesiologist would not use a
17	correctly? Did I read that correctly?	17	device in the OR that may cause a patient harm.
. 18	A. Yeah.	18	MR. GORDON: Object to the form of the
19	Q. Okay. Reading this e-mail today, you still	19	question.
20	have no concern with respect to a Bair Hugger being	20	Q. Correct?
21	contaminated and being used in the OR in a surgery?	21	A. I would not use a device from which I am
22	MR. GORDON: Object to the form of the	22	convinced that it would cause harm.
23	question.	23	Q. Okay. What evidence do you have well
24	A. Reading it, I can see that it's become	24	strike that.
25	contaminated. I don't see yet why it should not be	25	Based on this e-mail, are you aware that
	Page 70		Page 72
1	used in surgery.	1	and this is a 3M e-mail that the Bair Hugger can
2	Q. But they should be cleaned be before it's	2	become contaminated?
3	used in surgery again; correct?	3	A. Yes.
4	MR. GORDON: Object to the form of the	4	Q. You're aware of that; correct?
5	question, also lack of foundation.	5	A. Correct.
6	A. That particular unit, probably yes.	6	Q. You heard about it from before; correct?
7	Q. Because it's a potential source of	7	A. Yes.
8	contamination in the operating room; correct?	8	Q. Okay. What evidence do you have that
9	MR. GORDON: Object to the form of the	9	indicates to you that the Bair Hugger doesn't blow out
10	question, also lack of foundation.	10	bacteria onto the patient during use while being used
11	MS. DIFRANCO: I'll object, counsel. She's	11	in the OR?
12	never seen this e-mail before, so to make	12	A. None.
13	I mean she's a fact witness here to talk	13	Q. Okay. Well you're looking for evidence of
14	about what she knows about this. To make those I	14	the opposite, that it actually causes infection,
15	mean she's not an expert in this case. If	15	rather than
16	But go ahead, doctor, if you know the answer	16	A. Correct.
17	to his question.	17	Q the evidence that it actually does not
18	A. I actually don't. I don't.	18	cause infection.
19	Q. You agree with me that patient safety is	19	A. Correct.
20	paramount in in the practice of medicine; correct?	20	Q. Okay. You are aware that there was no
21	A. Absolutely.	21	validation study of the Bair Hugger before it was put
22	Q. And even you agree with me, as you being an	22	into use
	advisory to 3M and other companies that manufacture	23	MR. GORDON: Object to the form
23	an inorty to stit and onto companies that manufacture		
23 24	medical devices, patient safety is paramount; correct?	2.4	O in the intraoperatively.
23 24 25	medical devices, patient safety is paramount; correct? A. Correct.	24 25	Q in the intraoperatively.MR. GORDON: Object to the form of the

18 (Pages 69 to 72)

	Page 73		Page 75
1	question.	1	Q. So when I say a validation study, I'm
2	A. What is a validation study?	2	talking about a clinical study that proves that the
3	Q. There was no clinical study done regarding	3.	that that that shows that the Bair Hugger is
4	the safety of the Bair Hugger before it was put into	4	is effective and safe. Are you aware of any studies
5	use into the market in the United States.	5	that have done that
6	MR. GORDON: Object to the form of the	6	MR. GORDON: Same objections.
7	question.	7	Q prior to being put into the market?
8	A. I'm not sure there really wasn't.	8	MR. GORDON: Same objections.
9	Q. You're aware you're aware of clinical	9	A. Yeah. I really don't understand where
10	studies; correct?	10	you're going; that's why I have a problem.
11	A. Yes.	1.1	Q. Well you understand what clinical studies
12	Q. You're aware of 510 or 510(k) clearance.	-12	are are are done for; correct?
13	A. Right.	13	A. Yes.
14	Q. Okay. Are you aware that the Bair Hugger	14	Q. Okay. If there's no predicate device, then
15	unit, the 505, was a 510(k) clearance device?	15	you have to do a clinical study that shows the
16	A. Yes.	16	efficacy and safety of of the medical device;
17	 Q. Okay. So there's no clinical studies that 	17	correct?
18	were performed with respect to the 5 the 505 unit;	18	A. Right.
19	correct?	1.9	Q. None was done for the Bair Hugger; correct?
20	A. I guess yes, correct.	20	MR. GORDON: Object to the form of the
21	Q. Therefore, there's no clinical studies to	21	question, also lack of foundation.
22	show that the Bair Hugger was safe for use	.22	A. Yeah, an efficacy study was done.
23	intraoperatively before it went to the market.	23	Q. Huh?
24	MR. GORDON: Object to the form of the	24	A. I mean even my own study was an efficacy
25	question.	25	study.
1	A. I really don't want to answer that because	1 2	Q. But it wasn't a safety study.A. No, it was not.
2	there's no way to provide that data.	3	Q. Okay. Did you have any discussions with Dr.
3	Q. Well clinical studies indicate that the	4	Augustine regarding his allegations regarding the
4	product is safe; correct? MR. GORDON: Object to the form of the	5	safety of Bair Hugger?
5 6		6	A. No.
7	question.	7	MR. ASSAAD: Exhibit 229.
8	A. Clinical studies indicate that the product improves patient outcome.	8	(Exhibit 229 handed to the witness.)
		9	THE WITNESS: Thank you.
9 10	Q. And it also looks at the the risk factor; correct?	10	Q. Exhibit 229 is an e-mail from Dr. Sessler
.11	A. Therefore, it is safe.	11	with an attachment for PerfecTemp, PerfecTemp, and
12	Q. Okay. Therefore, it's safe. And and	12	attached to it is an article entitled "A Randomized
13	part of the criteria for a clinical study is safety;	13	Comparison of Intraoperative PerfecTemp and Forced-Air
14	correct?	14	Warming During Open Abdominal Surgery." Have you seen
15	A. Yes.	15	this article before?
16	Q. Okay. That criteria doesn't exist for a	16	A. I can't remember.
17	510(k); correct?	17	Q. Okay. The reason I want to ask you about it
18	A. This is correct.	18	is on your CV on page 16, talking about corporate
19	Q. Okay. Are you aware that the Bair Hugger	19	funding, you have listed "LMA-Perfect temperature
20	unit, the 505, the predicate device was a 1937 cast	20	versus Forced air warming," and I'm wondering if this
21	warmer manufactured in the United manufactured in	21	article is a result of your work even though you're
22	the United States?	22	not a named author on this subject matter.
23	A. No.	23	A. I can't remember. Sorry.
24	MR. GORDON: Object to the form of the	24	Q. You don't remember?
25	question, also lack of foundation.	. 25	A. I don't.

19 (Pages 73 to 76)

	Page 77		Page 79
1	Q. You don't remember sitting here today?	· 1	or not that was for this paper that's Exhibit No. 229?
2	A. Hmm?	2	MR. GORDON: Objection, lack of foundation.
3	Q. You don't remember.	3	A. I assume it was.
4	A. I don't remember.	4	Q. Have you seen this PowerPoint presentation
5	Q. Okay. Are you familiar with the PerfecTemp	5	before?
6	device?	6	A. If the study was done in Outcomes Research,
7	A. The PerfecTemp. Was it the LMA, the	7	probably. But I can't remember it.
8	No.	8	Q. Did you create this PowerPoint presentation?
9	Q. Okay.	- 9	A. No.
10	A. I mean at at at this second I can't	10	Q. If you go to page 10 and I apologize for
11	recall it.	11	the poor print job, but the printer at the hotel was
12	Q. It's a it's a conductive	12	not satisfactory.
13	A. I can't	13	A. Yeah.
14	Q. It's a conductive warming unit that lays on	14	Q. It says "Why PerfecTemp?" and the last
15	top of the operating room table.	15	bullet point says, "It does not blow It does not
16	A. Then I probably am, yes.	16	blowing air so it's totally silent with no chance of
17	Q. Let me	17	potential increase risk of contamination." Have you
18	A. No, I I I probably am.	18	seen that statement before?
19	Is it like a mattress?	19	A. I cannot remember it.
20	Q. Yes. And I'll give you some more in	20	Q. Okay. Do you recall anyone discussing the
21	A. Yeah. No, no, I I probably am.	21	risk of contamination with blowing air?
22	MR. ASSAAD: Mark this.	22	A. In that context, no.
23	A. It's actually in here. I don't	23	Q. Is this a document that was created by the
24	MR. ASSAAD: Did I give you two copies?	24	Department of Outcomes Research?
25	MS. DIFRANCO: No.	25	MR. GORDON: Objection, lack of foundation.
	- 50		D
n nacamana na raarahii	Page 78		Page 80
1	(Exhibit 240 was marked for	1	A. It looks like it.
2	(Exhibit 240 was marked for identification.)	2	A. It looks like it.Q. Sitting here today, do you have any reason
	(Exhibit 240 was marked for identification.) BY MR. ASSAAD:	2	A. It looks like it.Q. Sitting here today, do you have any reason to believe that this document wasn't created by
2 3 4	(Exhibit 240 was marked for identification.) BY MR. ASSAAD: Q. Exhibit 240 is a document I pulled off the	2 3 4	A. It looks like it. Q. Sitting here today, do you have any reason to believe that this document wasn't created by someone at Outcomes Research?
2	(Exhibit 240 was marked for identification.) BY MR. ASSAAD: Q. Exhibit 240 is a document I pulled off the internet entitled "LMA PerfecTemp versus Forced-air	2 3 4 5	A. It looks like it. Q. Sitting here today, do you have any reason to believe that this document wasn't created by someone at Outcomes Research? MR. GORDON: Same objection.
2 3 4 5 6	(Exhibit 240 was marked for identification.) BY MR. ASSAAD: Q. Exhibit 240 is a document I pulled off the internet entitled "LMA PerfecTemp versus Forced-air Warming."	2 3 4 5 6	 A. It looks like it. Q. Sitting here today, do you have any reason to believe that this document wasn't created by someone at Outcomes Research? MR. GORDON: Same objection. A. No.
2 3 4 5 6 7	(Exhibit 240 was marked for identification.) BY MR. ASSAAD: Q. Exhibit 240 is a document I pulled off the internet entitled "LMA PerfecTemp versus Forced-air Warming." A. Uh-huh.	2 3 4 5 6 7	 A. It looks like it. Q. Sitting here today, do you have any reason to believe that this document wasn't created by someone at Outcomes Research? MR. GORDON: Same objection. A. No. Q. And as you continue on, it talks about
2 3 4 5 6	 (Exhibit 240 was marked for identification.) BY MR. ASSAAD: Q. Exhibit 240 is a document I pulled off the internet entitled "LMA PerfecTemp versus Forced-air Warming." A. Uh-huh. Q. Department of Outcomes Research at the 	2 3 4 5 6 7 8	 A. It looks like it. Q. Sitting here today, do you have any reason to believe that this document wasn't created by someone at Outcomes Research? MR. GORDON: Same objection. A. No. Q. And as you continue on, it talks about subject selection and the hypothesis
2 3 4 5 6 7	(Exhibit 240 was marked for identification.) BY MR. ASSAAD: Q. Exhibit 240 is a document I pulled off the internet entitled "LMA PerfecTemp versus Forced-air Warming." A. Uh-huh. Q. Department of Outcomes Research at the Cleveland Clinic. I take it that is the department	2 3 4 5 6 7 8 9	 A. It looks like it. Q. Sitting here today, do you have any reason to believe that this document wasn't created by someone at Outcomes Research? MR. GORDON: Same objection. A. No. Q. And as you continue on, it talks about subject selection and the hypothesis A. Uh-huh.
2 3 4 5 6 7 8	 (Exhibit 240 was marked for identification.) BY MR. ASSAAD: Q. Exhibit 240 is a document I pulled off the internet entitled "LMA PerfecTemp versus Forced-air Warming." A. Uh-huh. Q. Department of Outcomes Research at the 	2 3 4 5 6 7 8 9	 A. It looks like it. Q. Sitting here today, do you have any reason to believe that this document wasn't created by someone at Outcomes Research? MR. GORDON: Same objection. A. No. Q. And as you continue on, it talks about subject selection and the hypothesis A. Uh-huh. Q and the protocol. Do you see all that?
2 3 4 5 6 7 8 9	(Exhibit 240 was marked for identification.) BY MR. ASSAAD: Q. Exhibit 240 is a document I pulled off the internet entitled "LMA PerfecTemp versus Forced-air Warming." A. Uh-huh. Q. Department of Outcomes Research at the Cleveland Clinic. I take it that is the department you work for, you're chair of. A. No, I'm not.	2 3 4 5 6 7 8 9 10	 A. It looks like it. Q. Sitting here today, do you have any reason to believe that this document wasn't created by someone at Outcomes Research? MR. GORDON: Same objection. A. No. Q. And as you continue on, it talks about subject selection and the hypothesis A. Uh-huh. Q and the protocol. Do you see all that? A. Yes, I do.
2 3 4 5 6 7 8 9	(Exhibit 240 was marked for identification.) BY MR. ASSAAD: Q. Exhibit 240 is a document I pulled off the internet entitled "LMA PerfecTemp versus Forced-air Warming." A. Uh-huh. Q. Department of Outcomes Research at the Cleveland Clinic. I take it that is the department you work for, you're chair of.	2 3 4 5 6 7 8 9 10 11	 A. It looks like it. Q. Sitting here today, do you have any reason to believe that this document wasn't created by someone at Outcomes Research? MR. GORDON: Same objection. A. No. Q. And as you continue on, it talks about subject selection and the hypothesis A. Uh-huh. Q and the protocol. Do you see all that? A. Yes, I do. Q. Would would it be fair to state that
2 3 4 5 6 7 8 9	(Exhibit 240 was marked for identification.) BY MR. ASSAAD: Q. Exhibit 240 is a document I pulled off the internet entitled "LMA PerfecTemp versus Forced-air Warming." A. Uh-huh. Q. Department of Outcomes Research at the Cleveland Clinic. I take it that is the department you work for, you're chair of. A. No, I'm not. Q. Vice chair. A. I was, yes.	2 3 4 5 6 7 8 9 10	 A. It looks like it. Q. Sitting here today, do you have any reason to believe that this document wasn't created by someone at Outcomes Research? MR. GORDON: Same objection. A. No. Q. And as you continue on, it talks about subject selection and the hypothesis A. Uh-huh. Q and the protocol. Do you see all that? A. Yes, I do. Q. Would would it be fair to state that this this document was created before the study was
2 3 4 5 6 7 8 9 10 11	(Exhibit 240 was marked for identification.) BY MR. ASSAAD: Q. Exhibit 240 is a document I pulled off the internet entitled "LMA PerfecTemp versus Forced-air Warming." A. Uh-huh. Q. Department of Outcomes Research at the Cleveland Clinic. I take it that is the department you work for, you're chair of. A. No, I'm not. Q. Vice chair. A. I was, yes. Q. Vice chair.	2 3 4 5 6 7 8 9 10 11	 A. It looks like it. Q. Sitting here today, do you have any reason to believe that this document wasn't created by someone at Outcomes Research? MR. GORDON: Same objection. A. No. Q. And as you continue on, it talks about subject selection and the hypothesis A. Uh-huh. Q and the protocol. Do you see all that? A. Yes, I do. Q. Would would it be fair to state that this this document was created before the study was performed?
2 3 4 5 6 7 8 9 10 11 12 13	(Exhibit 240 was marked for identification.) BY MR. ASSAAD: Q. Exhibit 240 is a document I pulled off the internet entitled "LMA PerfecTemp versus Forced-air Warming." A. Uh-huh. Q. Department of Outcomes Research at the Cleveland Clinic. I take it that is the department you work for, you're chair of. A. No, I'm not. Q. Vice chair. A. I was, yes. Q. Vice chair. And if you go to the third page, do you see	2 3 4 5 6 7 8 9 10 11 12 13	 A. It looks like it. Q. Sitting here today, do you have any reason to believe that this document wasn't created by someone at Outcomes Research? MR. GORDON: Same objection. A. No. Q. And as you continue on, it talks about subject selection and the hypothesis A. Uh-huh. Q and the protocol. Do you see all that? A. Yes, I do. Q. Would would it be fair to state that this this document was created before the study was performed? MR. GORDON: Object to the form of the
2 3 4 5 6 7 8 9 10 11 12 13 14	(Exhibit 240 was marked for identification.) BY MR. ASSAAD: Q. Exhibit 240 is a document I pulled off the internet entitled "LMA PerfecTemp versus Forced-air Warming." A. Uh-huh. Q. Department of Outcomes Research at the Cleveland Clinic. I take it that is the department you work for, you're chair of. A. No, I'm not. Q. Vice chair. A. I was, yes. Q. Vice chair.	2 3 4 5 6 7 8 9 10 11 12 13 14	 A. It looks like it. Q. Sitting here today, do you have any reason to believe that this document wasn't created by someone at Outcomes Research? MR. GORDON: Same objection. A. No. Q. And as you continue on, it talks about subject selection and the hypothesis A. Uh-huh. Q and the protocol. Do you see all that? A. Yes, I do. Q. Would would it be fair to state that this this document was created before the study was performed?
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20 (Pages 77 to 80)

	Page 81		Page 83
1	Q. Seeing this picture.	1	Q. Well
2	A. Of the device, yes.	2	Have you ever used the PerfecTemp in
3	Q. Okay. Which is on page three.	3	practice?
4	A. Yes.	4	A. No.
5	Q. Okay. Do you remember doing any part of the	5	Q. Do you recall any meetings with the with
6	testing or any part of the writing of the manuscript?	6	LMA, the manufacturer of PerfecTemp?
7	A. I don't.	7	A. Not nec
8	Q. Okay.	8	I might have been involved in one or
9	A. And I most likely didn't; otherwise, my name	-9	another, but I don't really recall them.
10	would be on the manuscript.	10	Q. Do you have any ownership or stock options
11	Q. Well based on your CV, you were definitely	11	in any medical-device company?
12	involved with respect to some sort of research done on	12	A. No.
13	PerfecTemp.	13	Q. Going back a couple
14	MR. GORDON: Object to the form of the	14	The use of Mistral by the Cleveland Clinic,
15	question.	15	have you had any discussions with anyone at 3M with
16	A. Hmm?	16	respect to the with respect to the Cleveland Clinic
17	Q. Correct?	17	using Mistral instead of Bair Hugger?
18	A. Not necessarily.	18	A. With the Cleveland Clinic, no.
19	Q. Well under corporate sources for for	19	Q. But outside the Cleveland Clinic, during any
20	research that you've done, you put on page 16 "LMA-	20	advisory meetings, telephone calls, meetings?
21	Perfect temperature versus Forced air warming," so you	21	A. I only recall
22	had some involvement in that research; correct?	22	I can be much more specific. So we have a
23	A. I I should, I might, but I really don't	23	personnel department who does all the buying, and she
24	recall much about that device.	24	just asked advised us about the efficacy, and that
25	Q. Let's take it in the negative. Is there	25	was my involvement.
	Page 82		Page 84
1	any	1	Q. But after the change
2	any I mean would you agree with me that you	2	Q. But after the changeA. Oh, after the
2 3	any I mean would you agree with me that you would not put anything on your CV indicating research	2	Q. But after the changeA. Oh, after theYeah.
2 3 4	any I mean would you agree with me that you would not put anything on your CV indicating research funding that you've obtained that was not research	2 3 4	 Q. But after the change A. Oh, after the Yeah. Q did 3M approach you and question why you
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	I mean would you agree with me that you would not put anything on your CV indicating research funding that you've obtained that was not research funding you obtained and did work on? A. Ideally, yes. Q. Okay. So you put this on your CV, so you actually were involved in some sort of research with PerfecTemp; correct? A. I must have been, yeah. Q. Okay. You're not disagreeing with that statement. A. I do not disagree. Q. All right. And and the research funding was \$196,000. A. Might have been, yes. Q. Well that's what it says on your CV, A. Yes. Q so that's correct; correct? A. That's correct then. Q. Okay. And that's a significant amount of funding; correct?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. But after the change A. Oh, after the Yeah. Q did 3M approach you and question why you guys changed from Bair Hugger to Mistral? A. Yes, they did. Q. And and to try to get the Cleveland Clinic back to the Bair Hugger? A. So far, very little. Q. When they approached you, who approached you? A. I don't recall the name exactly. It was Jay Jay I don't know his last name. Q. Issa? A. Yes. Q. And do you recall that conversation? A. I do. Q. And what what was the discussion? What's your what's your recollection of the discussion you guys had? A. They only wanted to know whether we think

21 (Pages 81 to 84)

	Page 85		Page 87
1	A in clinical use.	1	normothermia.
2	Q. And what was your response?	2	Prior to your 1996 study, was there any
3	A. At that point in time it was that I'm	3	evidence that normothermia reduced the incidence of
4	unsure.	4	infections?
5	Q. And at some point later on you changed your	5	A. I don't think that there was a clinical
6	opinion?	6	study before that.
7	A. Not yet. I'm actually	7	Q. Now my understanding is that you're of the
. 8	We are in the process of pulling data to	8	opinion that normothermia reduces normothermia
9	compare the devices.	9	during the intraoperative period, maintaining
10	Q. But at the time of the changeover, you	10	normothermia reduces the risk of wound infection.
11	thought it was as as efficacious as the Bair	11	A. Yes.
12	Hugger.	12	Q. Okay. It also reduces the risk of
13	A. I at the advice	13	transfusion.
14	My advice was it is as efficacious; however,	14	A. Yes.
15	after we've used it for six months, our CRNA thought	15	Q. And also I'm not sure if this is still
16	it wouldn't be.	16	your opinion today or not reduces the the length
17	O. Your excuse me?	17	of stay.
18	A. My providers in the room thought it wouldn't	18	A. I would have doubts in that regard.
19	be.	19	Q. Okay. So it would be fair to say that the
20	Q. Oh. And their basis was what?	20	current evidence does does not the current
21	A. Core temperature at the end of surgery.	21	reli the current reliable evidence strike that.
22	Q. Is there a study being performed between the	22	There's not enough current reliable evidence
23	efficacy of Mistral versus the efficacy of Bair	23	to formulate the opinion that maintaining normothermia
24	Hugger?	24	during the intraoperative period reduces the length of
25	A. Not yet.	25	stay for patients.
	120 100 900		
	Page 86		Page 88
1	Q. When you say "not yet," is it is it	1	A. I would agree, yes.
2	upcoming?	2	Q. Now you corrected me before with respect to
. 3	A. I've had it planned for more than half a	3 ·	hypothermia causes we were
. 4	year but just didn't get to it. So it should be	4	We were talking about the 2015 article in
5	upcoming.	5	Anesthesia and I said that it reduces bleeding, you
6	Q. Who is sponsoring it?	6	said no, reduces the risk of transfusion,
7	A. Nobody. It's a quality-improvement project	7	A. Correct.
8	within our department.	8	Q. Is there a difference?
9	Q. But sitting here today, there's no evidence	9	A. The only difference is that bleeding is very
10	that suggests one device is more efficacious than the	10	difficult to evaluate so there will be a very weak
11	other.	11	outcome, but of course you are correct, if you need
12	A. No.	12	more transfusions, you should bleed more.
13	Q. Was Dr. Sessler part of the agree the	13	Q. Okay. In the 1960 study 1996 study, did
14	discussion with respect to the changeover between the	14	you look at bleeding as well, or just
15	Bair Hugger unit and the Mistral unit?	15	A. Not in that particular study.
16	A. He was asked about his opinion in regard to	16	Q. Okay. And, of course, one of the benefits
17	efficacy, yes.	17	of of warming a patient is patient comfort.
18	Q. Okay. What was his opinion, do you recall?	18	A. I would not say "of course," but it should
19	A. Same thing	19	be.
20	Actually, very similar to mine, that he also	20	Q. Okay. Why wouldn't you say "of course?"
21	thought it would be as it will be very comparable	21	A. I'm not aware that there are lots of studies
22	to the Bair Hugger	22	that really looked at patient comfort.
23	Q. Okay.	23	Q. So there's no evidence today that
24	A in regards to heat transfer.	24	maintaining normothermia during the intraoperative
25	Q. Let's talk about your favorite subject,	25	period increases patient com comfort?
			-

	Page 89		Page 91
1	A. When? Intraoperative, post	1	A. Exactly, yes.
2	intraoperative, in their sleep, or	2	Q. Okay. Are you aware of any study with
3	Q. Let's talk intraoperatively.	3	respect to infection rates and maintaining
4	A. I I can't answer that.	4	normothermia besides your 1996 study?
5	Q. Okay. You can't answer that because there's	5	A. I think there was a repeti a second study
6	no evidence and no studies.	6	that was published,
7	A. No. Because I can't remember it.	7	Q. The Melling study?
		. 8	A the Melling study, thereafter.
. 8	Q. Okay. Okay. So you're aware you're	ı	- · · · · · · · · · · · · · · · · · · ·
9	aware sitting here today of no studies that looked at	9	Q. But isn't the Melling study prewarming?
10	that issue.	1.0	A. That's a difficult point. Yeah, they he
11	A. I'm not aware. I'm almost sure there are	11	did prewarming plus I think intraoperative warming,
12	some.	12	but it's hard to tell because I think he didn't report
13	Q. Now are there any other adverse	13	core temperatures, so
14	complications that occur with hypothermia that you've	14	But it doesn't matter. It it's about
15 '	looked at besides infection rates and transfusion?	15	maintenance of normothermia during surgery because
16	A. We looked at infection, transfusion,	16	that's what prewarming helps you with as well.
17	post-operative I think we did post-operative	17	Q. I understand that. And there's also the new
18	recovery, and duration of time in the recovery room.	18	area where, you know
19	There are studies about drug metabolism, but I think I	19	A. Which
2.0	wasn't involved in any one of those.	20	Q you know, pre I'll get to it later,
21	Q. And this is during the intraoperative	21	but the prewarming for 30 minutes,
22	period; correct?	22	A. Oh, yeah.
23	A. Yes.	23	Q you know, the extremities have a big
24		24	difference because of Seconal thermodynamics.
25	Q. We're look we're looking at the intraoperative period?	25	A. Exactly.
	Page 90		Page 92
1	A. We always look at the intraoperative period.	1	Q. We'll get to that later.
2	Q. All right. And you also looked at length of	2	But my question is: Sitting here today with
3	stay, but the evidence today is not strong.	3	respect to the Melling article and I have a copy of
4	A. Length of stay in the recovery room is	4	it for you if you want to look at it
5	significant, length of stay in the hospital is	5	A. Huh-uh.
6	questionable.	6	Q where is any evidence that there was any
7	Q. Okay. The recovery duration and time in the	7	intraoperative warming? Because I heard the same
8	operating room, what study was that?	8	thing at Dr. Sessler's deposition where we read the
9	A. That was only part of the '96 paper.	9	article
10	Q. Okay.	10	MR. ASSAAD: Oh, sorry, that's mine. That's
		1	
11	A. Or in fact, no, there was a second a	11	your copy.
12	publication from that by Lenhardt about at the same	12	(Exhibit 241 was marked for
13	time.	13	identification.)
14	Q. Okay. Was it the same using the same	14	MR. GORDON: Are you done with your
15	data?	15	question?
16	A. Using same data.	16	MS. DIFRANCO: Do you want an answer to the
17	Q. Okay. So the results are the same in both	17	question?
18	papers.	18	MR. ASSAAD: I was marking it and
19	A. I think duration of recovery was not in the	19	Yeah, I'm done with that question.
20	first paper at all.	20	MR. GORDON: I object to the form of the
21	Q. Okay. It was just length of stay in the	21	question.
22	first paper.	22	MS. DIFRANCO: Could you hear his question?
_	A. Uh-huh.	23	MR. ASSAAD: I'll re
23	AND WAR HUMB	1 ~~	
23 24	O Okay And the duration of recovery that	24	Let me withdraw the question I'll restate
23 24 25	 Q. Okay. And the duration of recovery, that was for colorectal patients. 	24 25	Let me withdraw the question. I'll restate it.

23 (Pages 89 to 92)

	Page 93		Page 95
1	Q. Exhibit 241 is an article titled "Effects of	1	at the article to determine whether or not
2	preoperative warming on the incidence of wound	2	intraoperative warming was used?
3	infection after clean surgery: a randomised	3	A. Is it relevant?
4	controlled trial" authored by Andrew Melling, Ba	4	Q. It is relevant because we're talking about
5	Baqar Ali, Eileen Scott and David Leaper.	-5	intraoperative warming in this case and
6	A. Uh-huh.	6	A. No. But is it relevant for your for your
, 7	Q. Are you familiar with this article?	7	upcoming questions? Because I cannot figure it out
8	A. Yes, I am.	8.	from whatever is written here.
9	Q. Okay. And we were discussing this article,	9	Q. Well how else would you figure it out if
10	and it's my understanding that they only looked at	10	it's not in the article?
11	prewarming patients and there's no mention of	11	A. You can't.
12	intraoperative warming. Do you agree with that?	12	Q. Okay. So you can't assume, sitting here
13	MR. GORDON: Object to the form of the	13	today, that intraoperative warming was used in the
14	question.	14	Melling study; correct?
15	A. I can't remember. I mean I can try to find	15	A. So poorly written.
16	it here.	16	Yeah, correct.
17	Q. Well let me let me backtrack and maybe	17	Q. Okay. So right now the only article that
18	this will help you remember, And maybe it goes back	18	that looked at intraoperative warming and infection
19.	even further.	19	rates is your 1996 Kurz article; correct?
20	You agree with me that intraoperative	20	A. Give me one second.
21	warming is unnecessary for surgeries that last less	21	Yes, correct.
22	than an hour.	. 55	Q. My question, from my last question; correct?
23	A. I'm not sure.	23	A. Yes.
24	Q. Okay. There's no evidence that	24	Q. Okay. Do you know David Leaper?
25	intraoperative warming is required for surgeries	25	A. No, I don't. Huh-uh.
	Page 94		Page 96
1	or or is beneficial for the patient in surgeries	1	Q. And you're aware, if you look at the con
2	that last less than an hour.	2	contributors on ar on Exhibit No. 291, Augustine
3	A. Most likely, yeah.	3	Medical was contributed to the was acknowledged
4	Q. And even the SCIP protocols, before they	4	for its consum provision of consumables for the
5	were retracted, only required thermal regulation for	5	Bair Hugger blankets.
6	surgeries lasting longer than an hour.	6	THE REPORTER: It's Exhibit 241.
7	A. I know, yeah.	7	THE WITNESS: Yes.
8	Q. Okay. If you look at page three of this	8	MR. ASSAAD: 241, I'm sorry.
9	of article Exhibit No. 241, do you see where the	9	A. Was it?
10	length of surgery the average length of surgery,	10	Q. Under "Acknowledgments."
11	they're all less than one hour?	11	A. "Acknowledgments." Yes.
12	A. Uh-huh.	12	Q. And is it fair that Augustine Medical also
13	THE REPORTER: Your answer?	13	contributed to your 1996 study?
14	Q. Do you see that?	14	MR. GORDON: Object object to the form of
15	A. Yes.	15	the question.
16	Q. Would that refresh your recollection of	16	A. Most likely, yes.
17	whether or not intraoperative warming would have been	17	Q. But he wasn't involved in any way with
18	used during this time period?	18	respect to the draft of the manuscript.
19	A. No, not at all.	19	A. No.
20	Q. Okay. Are you aware, back in 2001, whether	20	Q. Okay. You wouldn't allow that; correct?
20	or not intraoperative warming was the standard of care	21	A. No.
21		22	Q. Okay. Now does the degree below core
	with regard to surgeries lasting less than an hour?		
21 22 23	A. I'm not. I would assume it was, but I I	23	temperature have an effect on the risk of transfusion
21 22			temperature have an effect on the risk of transfusion or the risk of infection? A. I assume you mean the depth of hypothermia.

24 (Pages 93 to 96)

I '	Page 97	Page 99
1	Q. Yes, the depth of hyp	1 A. They were probably longer, but there are
2	A. Yes, I I think so.	2 even today there are large differences where the
3	Q. You think so, but there's there's no	3 surgery is done in regards to length, so I I don't
4	studies at this point with respect to withdraw	4 want to say
5	that.	5 Q. You don't want to gen
6	With respect to infections, there are no	6 A they were longer at that time.
7	studies on that issue; correct?	7 Q. Is there any other reason why you only look
8	A. On the specific issue of depth, no.	8 at colorectal as compared to, say, you know, any other
9	Q. Okay. The 2015 article looked at the depth	9 type of surgery?
10	of hypothermia and the risk of of transfusion.	10 A. No, there isn't,
	A. Absolutely, yes.	11 Q. It's it's more you need a lot more
12	Q. Okay. In this retrospective study that	12 patients looking at other to power
13	you're going to be doing that's sponsored by 3M, are	13 To power a study of a different type of
14	you going to be looking at the depth of hypothermia	3.
15		
l .	with respect to infection rates?	15 A. Yes.
16	A. Yes.	16 (Discussion off the stenographic record.)
17	Q. Okay. Are you are you looking at all	17 (Exhibit 242 was marked for
18	surgeries, or just colorectal?	18 identification.)
19	A. I think it's only colorectal.	19 BY MR. ASSAAD:
20	Q. Why do you only look at colorectal	20 Q. What's been marked as Exhibit 242 is an
21	surgeries?	21 article in the New England Journal of Medicine titled
22	A. Because they have the highest incidence of	22 "PERIOPERATIVE NORMOTHERMIA TO REDUCE THE INCIDENCE OF
23	infections after surgery and so you need a smaller	23 SURGICAL-WOUND INFECTION AND SHORTEN HOSPITALIZATION"
24	number of patients, and secondly, because our	24 dated May 9th, 1996, in which you're the first author.
25	colorectal database is the best surgical followup	25 A. Yeah.
	Page 98	Page 100
1	database where we can absolutely rely on the infection	1 Q. You are familiar with this article; correct?
2	data.	2 A. Yes.
3	Q. When you say "we," you're talking about the	3 Q. And if you look at the the small print in
4	Cleveland Clinic, or are you talking about nationally,	4 the bottom left-hand corner of the first page, it
5.	globally?	5 states, "Supported in grants in part by grants from
6	A. We, the Cleveland Clinic.	6 'the National Institute of Health, by the Joseph Drown
7	Q. Okay. Colorectal surgeries usually take	7 and Max Kade Foundations, and by Augustine Medical
8	roughly, on average, about four hours; correct?	8 Incorporated."
9	A. Three hours I would expect.	9 A. Uh-huh, yes.
10	Q. Three hours now?	10 Q. So Augustine, Dr. Augustine, helped fund
10 11	A. Uh-huh.	11 this study.
		11 this study. 12 MR. GORDON: Object to the form of the
11	A. Uh-huh.	11 this study.
11 12	A. Uh-huh.Q. I think back in 1996 it was around four	11 this study. 12 MR. GORDON: Object to the form of the
11 12 13	A. Uh-huh.Q. I think back in 1996 it was around four hours.	11 this study. 12 MR. GORDON: Object to the form of the question.
11 12 13 14	A. Uh-huh.Q. I think back in 1996 it was around four hours.A. Oh, it was much longer, yeah. And they were	11 this study. 12 MR. GORDON: Object to the form of the 13 question. 14 A. Most likely did, yes.
11 12 13 14 15	 A. Uh-huh. Q. I think back in 1996 it was around four hours. A. Oh, it was much longer, yeah. And they were all open. 	 this study. MR. GORDON: Object to the form of the question. A. Most likely did, yes. Q. When you say "Supported in part by
11 12 13 14 15	 A. Uh-huh. Q. I think back in 1996 it was around four hours. A. Oh, it was much longer, yeah. And they were all open. Q. And all 	 this study. MR. GORDON: Object to the form of the question. A. Most likely did, yes. Q. When you say "Supported in part by grants," grants would be money; correct?
11 12 13 14 15 16	 A. Uh-huh. Q. I think back in 1996 it was around four hours. A. Oh, it was much longer, yeah. And they were all open. Q. And all And back then in 1996, around that time, a 	 this study. MR. GORDON: Object to the form of the question. A. Most likely did, yes. Q. When you say "Supported in part by grants," grants would be money; correct? A. Absolutely.
11 12 13 14 15 16 17	 A. Uh-huh. Q. I think back in 1996 it was around four hours. A. Oh, it was much longer, yeah. And they were all open. Q. And all And back then in 1996, around that time, a lot of surgeries took a lot longer than they do today. 	11 this study. 12 MR. GORDON: Object to the form of the question. 14 A. Most likely did, yes. 15 Q. When you say "Supported in part by grants," grants would be money; correct? 17 A. Absolutely. 18 Q. Okay. Who created the protocols for this
11 12 13 14 15 16 17 18	 A. Uh-huh. Q. I think back in 1996 it was around four hours. A. Oh, it was much longer, yeah. And they were all open. Q. And all And back then in 1996, around that time, a lot of surgeries took a lot longer than they do today. MR. GORDON: Objection to the form of the question. 	11 this study. 12 MR. GORDON: Object to the form of the question. 14 A. Most likely did, yes. 15 Q. When you say "Supported in part by grants," grants would be money; correct? 17 A. Absolutely. 18 Q. Okay. Who created the protocols for this study? 20 A. That was Dan Sessler and me.
11 12 13 14 15 16 17 18 19 20	 A. Uh-huh. Q. I think back in 1996 it was around four hours. A. Oh, it was much longer, yeah. And they were all open. Q. And all And back then in 1996, around that time, a lot of surgeries took a lot longer than they do today. MR. GORDON: Objection to the form of the question. A. Not necessarily. 	this study. MR. GORDON: Object to the form of the question. A. Most likely did, yes. Q. When you say "Supported in part by grants," grants would be money; correct? A. Absolutely. Q. Okay. Who created the protocols for this study? A. That was Dan Sessler and me. Q. Okay. And this is when you were a fellow;
11 12 13 14 15 16 17 18 19 20 21	 A. Uh-huh. Q. I think back in 1996 it was around four hours. A. Oh, it was much longer, yeah. And they were all open. Q. And all And back then in 1996, around that time, a lot of surgeries took a lot longer than they do today. MR. GORDON: Objection to the form of the question. A. Not necessarily. Q. All right. 	this study. MR. GORDON: Object to the form of the question. A. Most likely did, yes. Q. When you say "Supported in part by grants," grants would be money; correct? A. Absolutely. Q. Okay. Who created the protocols for this study? A. That was Dan Sessler and me. Q. Okay. And this is when you were a fellow; correct?
11 12 13 14 15 16 17 18 19 20 21 22 23	 A. Uh-huh. Q. I think back in 1996 it was around four hours. A. Oh, it was much longer, yeah. And they were all open. Q. And all And back then in 1996, around that time, a lot of surgeries took a lot longer than they do today. MR. GORDON: Objection to the form of the question. A. Not necessarily. Q. All right. A. It went down in a very different way. 	this study. MR. GORDON: Object to the form of the question. A. Most likely did, yes. Q. When you say "Supported in part by grants," grants would be money; correct? A. Absolutely. Q. Okay. Who created the protocols for this study? A. That was Dan Sessler and me. Q. Okay. And this is when you were a fellow; correct? A. Exactly.
11 12 13 14 15 16 17 18 19 20 21	 A. Uh-huh. Q. I think back in 1996 it was around four hours. A. Oh, it was much longer, yeah. And they were all open. Q. And all And back then in 1996, around that time, a lot of surgeries took a lot longer than they do today. MR. GORDON: Objection to the form of the question. A. Not necessarily. Q. All right. 	this study. MR. GORDON: Object to the form of the question. A. Most likely did, yes. Q. When you say "Supported in part by grants," grants would be money; correct? A. Absolutely. Q. Okay. Who created the protocols for this study? A. That was Dan Sessler and me. Q. Okay. And this is when you were a fellow; correct?

25 (Pages 97 to 100)

Page 101 Page 103 1 Q. Okay. And who did -- who -- who wrote 1 It went down to 33, but 34, 34.5 were very 2 the --2 common. 3 3 Who wrote most of the manuscript? Q. Okay. So over time that has changed. A. I want to say both of us, but he probably 4 A. Absolutely. 5 wrote a little bit more than I did because he was my 5 Q. Okay. Now it's my understanding that in 6 this study you had two groups, a control group and 6 O. Okay. And who is Rainer Lenhardt? 7 a -- and a group that was warmed with a Bair Hugger 7 8 8 A. He was in -- a colleague at the University unit; correct? 9 of Vienna where this study was conducted. 9 A. Yes, that's correct. 10 Q. And why was the study conducted in the 10 Q. And initially you were looking to do this 11 University of Vienna -- Vienna as compared to San 11 for 400 patients, but after 200 patients you -- you --12 Francisco where you were located? 12 you -- you had enough data to get a -- a p-value that A. Because this study actually happened --13 was -- that showed statistical significance so you 13 Because Vienna was my home institution, and 14 14 ended the study; correct? part of admission when you do a fellowship in another 15 15 A. Yes. 16 Q. And the control group -- well let me go 16 country is to bring knowledge back to your home 17 17 institution, get them involved in whatever activities back. Before warming was used in the University of 18 you were sent out to learn. 18 19 Vienna, did they use cotton blankets to keep patients 19 Q. Uh-huh. 20 A. And so --20 21 And the second part was that usually the 21 A. We have used the oper -- the -- how do you 22 universities, the main campus didn't have a large 22 call the --23 population as opposed to -- for the patients needed --23 Q. Drapes? 2.4 needed for this study, and in Vienna we did. 2.4 A. Drapes, yeah. 25 Q. And -- okay. I have a couple questions. 25 Q. No blankets, no convective --Page 102 Page 104 Actually, I have many questions. 1 A. No warmed blankets. 1 2 If you look at the first paragraph, you 2 Q. Okay. Okay. In your study, you decided to 3 3 know, where it starts with "Wound...," about twouse the Bair Hugger on for both patients, just had the 4 thirds of the way down it says, "Mild perioperative 4 heating level at a different -- one was ambient and 5 hypothermity -- hypothermia (approximately two degrees 5 one was heat; correct? 6 6 Celsius below the normal core body temperature) is A. Uh-huh. Yes. 7 7 common in colon surgery." Q. Why for the control which you decided to use 8 8 A. Uh-huh, yes. the ambient temperature, which takes basically 9 Q. You told me before that mild hypothermia was 9 operating room temperature and pushes it over the 10 35.5 degrees Celsius, but if normal core body 10 patient, instead of just keeping the Bair Hugger off? 11 11 temperature is about 36.5, why is mild hypothermia in A. We deemed that --12 12 this case two degrees Celsius below instead of one? You could have done that just as well, but 13 we deemed that the cleaner study design, because our 13 A. I guess we just called it differently more 14 than 20 years ago, because what is mild -- was 14 outcome was in many ways also dependent on surgeons, 15 considered mild now was, 20 years ago when nobody was 15 and we wanted to be -- the surgeons -- to have the warmed in the OR, somewhat different. 16 surgeons and everybody in the OR blinded. 16 17 Q. I understand that. But would you agree with 17 Q. Okay. 18 18 me that taking, you know, anywhere between 18 to 22 A. So a core temperature of 34 was something we 19 19 saw every day then, so wasn't a big deal. If we would degrees Celsius air that's blowing out of a Bair 20 20 see it today, we would say it's severe hypothermia. Hugger blanket at the ambient temperature, actually 21 Q. Okay. And did you see core temperatures of 21 having cooling effect on the patient? 22 34 a lot back then, or was it --22 MR. GORDON: Object to the form of the 23 A. Yes. 23 question. 24 24 Q. -- 34.5, thirty --A. I don't know. Might have. 25 Q. Well when you sit in front --A. Anywhere. It was rare below --

26 (Pages 101 to 104)

	Page 105		Page 107
1	When you get hot and you put a fan in front	1	them, or do they have
2	of you, don't you feel cooler?	2	A. No.
3	A. Oh yeah, but I'm not anesthetized I hope.	3	Q blankets on top of them?
4	Q. Okay. So you think when you're	4	A. Oh, I assume there are blankets on top of
5	anesthetized, the cooling effect of blowing air is	5	them.
6	different than when you're not anesthetized?	6	Q. Okay. So they were being warmed with
7	A. Absolutely.	7	blankets. Okay. So we're kind of looking at apples
8	Q. Oh, okay. So you don't think the cooling	8	and oranges, putting cold air above a patient and
9	air that's running over your body is going to take the	9	ambient temperature being 24 degrees.
10	moisture and and bring any type of warmth that's	10	A. That's fine, yeah.
11	coming from your body away from your body.	11	Q. Do you agree?
12	A. That's not what I said. What you say now is	12	A. I do agree.
13	correct.	13	Q. Okay. So what other studies do you show
1.4	Q. You're saying that the Bair Hugger blowing	14	that 22 degrees of ambient air blowing over a patient
15	at ambient temperature can have a cooling effect on a	15	through a Bair Hugger blanket doesn't cause a cooling
16	patient.	16	effect?
17	A. It could have, yes, depending on the	17	
18	temp the ambient temperature.	18	Q. Okay. If you look at the at the study,
19	Q. Well what's the ambient temperature of an	19	on Table 1 you see the "Final core temperature" for
20	operating room?	20	the hypothermic grouping, 34.7 degrees plus or
21	A. It's in the paper I assume. It should be in	21	minus .6 degrees; correct?
22	the Table 1	22	A. Wait, wait, I I don't have it yet. Where
23	Q. Okay.	23	is the core temperature?
24	A or somewhere I hope.	24	You're in Table 1.
25	Q. 21.9 degrees or 22.1, depending on the on	25	Q. Table 1, two-thirds of the way down under
	Daga 106		
	Page 106		Page 108
1	the control group; correct?	1	Page 108 200 ambient temperature.
1 2	•	1 2	
	the control group; correct?	l	200 ambient temperature.
2	the control group; correct? A. So 22 will not have a large cooling effect.	. 2	200 ambient temperature. A. Yes.
2 3	the control group; correct? A. So 22 will not have a large cooling effect. Q. Okay.	. 2	200 ambient temperature.A. Yes.Q. I think you're at the wrong
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2 3 4 5 6	the control group; correct? A. So 22 will not have a large cooling effect. Q. Okay. A. Nineteen would. Q. Nineteen would, but 22 And what's your basis behind that?	2 3 4 5 6	 200 ambient temperature. A. Yes. Q. I think you're at the wrong Keep on going down. I'm looking at "Intraoperative variables," final section. A. Oh, yeah. I was thinking because mine
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	Page 109		Page 111
1	retrospective study, which only included patients that	1	Q. Okay. Does that go for all surgeries or
2	were warmed.	2	just colorectal?
3	Q. By which method, passive warming?	3	A. It's different for different surgeries and
4	A. No. All forced-air warming.	4	patient population.
5	Q. And with respect to strike that.	5	Q. All right. And then about the next
6	These are surgeries that lasted three hours;	6	paragraph you write, on the second sentence,
7	correct?	7	"Perioperative hypothermia persisted for more than
8	A. Yes.	8	four hours and thus included the decisive period for
9	Q. So this is three hours of no warming;	9	establishing an infection."
10	correct?	10	A. Correct.
11	A. Yes.	11	Q. I'm trying to understand this. Are are
12	Q. And three hours of air Bair Hugger being	12	you saying that you're more susceptible for an
13	on blowing ambient air over the patient; correct?	13	infection when you're hypothermic as compared to when
14	A. Not correct. It's three hours of active	14	you're not hypothermic?
15	warming with the Bair Hugger at 42 degrees, or three	15	A. To a certain degree, yes.
16	hours of having the Bair Hugger's control with ambient	16	Q. Okay.
17	warming.	17	A. Actually, it's exactly what I'm saying.
18	Q. Which is just which is just ambient	18	Q. Okay. And if I understand you correctly,
19	air	19	you're saying because the hypothermia lasted for four
20	A. Right.	20	hours, because a surgery was three hours plus, that
21	Q which is at 22 degrees.	21	that established enough time for the host defense
22	A. Right.	22	system to become weakened and therefore unable to
23	Q. Okay. And let's correct that one minute.	23	fight off a bacteria combination con
24	It wasn't at 42 degrees for the for the Bair	24	contamination, increasing the risk of surgery.
25	Hugger, it was at 40 degrees; correct?	25	A. Yes, that's part of it.
1	A. Yeah. Might have been, yeah.	1	Q. What's the other part?
2	Q. Okay. Well if you look at the page before	2	A. The other part is that hypothermia causes
3	that	3	vasoconstriction, which decreases perfusion to the
4	A. I trust you.	4	wound, and therefore nutrients, important nutrients, oxygen and other things that the wound needs for
5	Q. Okay. Did you look at what the temperatures	5	• •
6	were at strike that.	6 7	healing, is not getting there.
7	Under the "Discussion" period, you		Q. At what point does hypothermia cause
8	"Discussion" section you write, "The initial hours	8	vasoconstriction?
9	after bacterial contamination are a decisive period	9 10	A. That depends on the patient's demographic,
10	for the establishment of infection." Did I read that	11	the anesthetic used, the dose of the anesthetic used.
11	correctly?	12	So there are various different factors. Q. But if you took best-case scenario, like
12	A. You	13	
13	Absolutely. Q. What do you mean by that?	13	Like what's the highest degree you saw of vasoconstriction below the core temperature?
14 15		15	A. With a low dose of anesthetic you can get
16	A. That a big An infection in a patient is usually	16	core vasoconstriction within a degree.
17	established during the initial hours of surgery, so	17	Q. One degree?
18	it's it's not that it happens five days after	18	A. Yes.
19	surgery, it pretty much happens right away, and it's	19	Q. Okay.
20	exactly why we give antibiotics before surgery or	20	A. With usually-used doses, you probably tend
4 0	right before surgery and not just in the middle or	21	to go two degrees.
		22	Q. Two degrees?
21	whenever we think at it		S. Tuo aobioni
21 22	whenever we think of it, O So you're saying the the the		A. (Nodding.)
21 22 23	Q. So you're saying the the the the	23	A. (Nodding.) O. Is that a yes?
21 22			A. (Nodding.)Q. Is that a yes?A. Yes.

28 (Pages 109 to 112)

	Page 113		Page 115
1	Q. Okay. So if a patient is one de like at	1	BY MR. ASSAAD:
2	35 degrees, can you sit here and tell me today what is	2	Q. All right. If you look at on Exhibit No.
3	the risk relative risk factor of that patient	3	218, take a look at those Bates numbers at the bottom
4	getting an infection?	4	that start with 3M.
5	A. No.	5	A. Uh-huh.
. 6	Q. What about at 35 degrees or I mean 34	6	Q. If you look at 3M that ends in 445, like
7	degrees? That would be this study; correct?	7	three pages on the back side
8	A. Yeah. You could calculate the number needed	8	A. Yeah.
9	to treat from that study. I don't know what it is.	9	Q. Well let me go back. Let me just explain
. 10	Q. Okay. Does hypothermia	10	what this document is. This document was produced by
11	You mentioned earlier that it depends on	11	3M. If you look at the first page, it's dated October
12	your initial core temperature; correct? The delta.	12	18th, 2012, "Global Patient Warming Advisory Board
13	A. Yes.	13	meeting," and it's the minutes of that meeting.
14	Q. Okay. So, for example, if I am have an	14	A. Uh-huh.
15	initial core temperature of high, like 37.5, are	15	Q. And you're listed as you and Daniel
16	you going to be seeing the effects at 36.5 because	16	Sessler and a bunch of other people are listed at that
17	I'm I'm a degree below?	17	meeting.
18	A. We don't know.	1.8	Do you recall being at that meeting?
19	Q. Okay. And the infections you were looking	19	A. Yes, I do.
20	at in this case, they were a lot of them were	20	Q. Okay. Do you recall discussing the troponin
21	superficial infections; correct?	21	study proposal?
22	A. Yes.	22	A. I do.
23	Q. Okay. None of them dealt with deep	23	Q. Okay. If you look back on the page, it
24	infections; correct?	24	says, "Kurz 1996 SSI paper limitations: only 200
25	A. That's not correct. There should have been	25	patients, mostly superficial infections with few
	Page 114		Page 116
1 1		i .	
1	deep	1	clinical consequences (we should focus on deep
2	We used the CDC criteria for infections.	. 2	tissue/organ SSIs)"
2	We used the CDC criteria for infections. How many were deep I can't remember, or whether any	2	tissue/organ SSIs)" Did I read that correctly?
2 3 4	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What	2 3 4	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do.
2 3 4 5	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What where is it? I don't know.	2 3 4 5	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do. Q. It says, "the factor of 3 risk increase
2 3 4 5 6	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What where is it? I don't know. Most likely the majority were superficial.	2 3 4 5 6	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do. Q. It says, "the factor of 3 risk increase is not plausible (30 or so is is more likely)."
2 3 4 5 6 7	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What where is it? I don't know. Most likely the majority were superficial. Yeah.	2 3 4 5 6 7	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do. Q. It says, "the factor of 3 risk increase is not plausible (30 or so is is more likely)." A. Yes.
2 3 4 5 6	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What — where is it? I don't know. Most likely the majority were superficial. Yeah. Q. Would you agree with me that of the 200	2 3 4 5 6 7 8	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do. Q. It says, "the factor of 3 risk increase is not plausible (30 or so is is more likely)." A. Yes. Q. Do you agree with that statement?
2 3 4 5 6 7 8 9	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What where is it? I don't know. Most likely the majority were superficial. Yeah. Q. Would you agree with me that of the 200 patients, the ones that got infection, they were	2 3 4 5 6 7 8 9	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do. Q. It says, "the factor of 3 risk increase is not plausible (30 or so is is more likely)." A. Yes. Q. Do you agree with that statement? A. Absolutely.
2 3 4 5 6 7 8 9	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What where is it? I don't know. Most likely the majority were superficial. Yeah. Q. Would you agree with me that of the 200 patients, the ones that got infection, they were mostly superficial infections with few clinical	2 3 4 5 6 7 8 9	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do. Q. It says, "the factor of 3 risk increase is not plausible (30 or so is is more likely)." A. Yes. Q. Do you agree with that statement? A. Absolutely. Q. Okay. So are are you saying that based
2 3 4 5 6 7 8 9 10	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What where is it? I don't know. Most likely the majority were superficial. Yeah. Q. Would you agree with me that of the 200 patients, the ones that got infection, they were mostly superficial infections with few clinical consequences?	2 3 4 5 6 7 8 9 10	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do. Q. It says, "the factor of 3 risk increase is not plausible (30 or so is is more likely)." A. Yes. Q. Do you agree with that statement? A. Absolutely. Q. Okay. So are are you saying that based on today's knowledge, that if a patient becomes
2 3 4 5 6 7 8 9 10 11 12	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What where is it? I don't know. Most likely the majority were superficial. Yeah. Q. Would you agree with me that of the 200 patients, the ones that got infection, they were mostly superficial infections with few clinical consequences? A. I would agree with that, yes.	2 3 4 5 6 7 8 9 10 11 12	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do. Q. It says, "the factor of 3 risk increase is not plausible (30 or so is is more likely)." A. Yes. Q. Do you agree with that statement? A. Absolutely. Q. Okay. So are are you saying that based on today's knowledge, that if a patient becomes hypothermic, that you're only going to see a 30-
2 3 4 5 6 7 8 9 10 11 12 13	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What where is it? I don't know. Most likely the majority were superficial. Yeah. Q. Would you agree with me that of the 200 patients, the ones that got infection, they were mostly superficial infections with few clinical consequences? A. I would agree with that, yes. Q. Okay. And would you agree with me today	2 3 4 5 6 7 8 9 10 11 12 13	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do. Q. It says, "the factor of 3 risk increase is not plausible (30 or so is is more likely)." A. Yes. Q. Do you agree with that statement? A. Absolutely. Q. Okay. So are are you saying that based on today's knowledge, that if a patient becomes hypothermic, that you're only going to see a 30-percent reduction or or warming is only going to
2 3 4 5 6 7 8 9 10 11 12 13	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What where is it? I don't know. Most likely the majority were superficial. Yeah. Q. Would you agree with me that of the 200 patients, the ones that got infection, they were mostly superficial infections with few clinical consequences? A. I would agree with that, yes. Q. Okay. And would you agree with me today that if you if you looked at what was considered	2 3 4 5 6 7 8 9 10 11 12 13 14	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do. Q. It says, "the factor of 3 risk increase is not plausible (30 or so is is more likely)." A. Yes. Q. Do you agree with that statement? A. Absolutely. Q. Okay. So are are you saying that based on today's knowledge, that if a patient becomes hypothermic, that you're only going to see a 30-percent reduction or or warming is only going to reduce those patients strike that maintaining
2 3 4 5 6 7 8 9 10 11 12 13 14 15	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What where is it? I don't know. Most likely the majority were superficial. Yeah. Q. Would you agree with me that of the 200 patients, the ones that got infection, they were mostly superficial infections with few clinical consequences? A. I would agree with that, yes. Q. Okay. And would you agree with me today that if you if you looked at what was considered hypothermia today with colorectal surgery, you're	2 3 4 5 6 7 8 9 10 11 12 13 14 15	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do. Q. It says, "the factor of 3 risk increase is not plausible (30 or so is is more likely)." A. Yes. Q. Do you agree with that statement? A. Absolutely. Q. Okay. So are are you saying that based on today's knowledge, that if a patient becomes hypothermic, that you're only going to see a 30-percent reduction or or warming is only going to reduce those patients strike that maintaining normothermia in colorectal patients will only reduce
2 3 4 5 6 7 8 9 10 11 12 13 14 15	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What — where is it? I don't know. Most likely the majority were superficial. Yeah. Q. Would you agree with me that of the 200 patients, the ones that got infection, they were mostly superficial infections with few clinical consequences? A. I would agree with that, yes. Q. Okay. And would you agree with me today that if you — if you looked at what was considered hypothermia today with colorectal surgery, you're expecting, instead of a three-fold reduction in	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do. Q. It says, "the factor of 3 risk increase is not plausible (30 or so is is more likely)." A. Yes. Q. Do you agree with that statement? A. Absolutely. Q. Okay. So are are you saying that based on today's knowledge, that if a patient becomes hypothermic, that you're only going to see a 30-percent reduction or or warming is only going to reduce those patients strike that maintaining normothermia in colorectal patients will only reduce the infection rate by approximately 30 percent or so?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What — where is it? I don't know. Most likely the majority were superficial. Yeah. Q. Would you agree with me that of the 200 patients, the ones that got infection, they were mostly superficial infections with few clinical consequences? A. I would agree with that, yes. Q. Okay. And would you agree with me today that if you — if you looked at what was considered hypothermia today with colorectal surgery, you're expecting, instead of a three-fold reduction in infections, about 30 percent? That would be your	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do. Q. It says, "the factor of 3 risk increase is not plausible (30 or so is is more likely)." A. Yes. Q. Do you agree with that statement? A. Absolutely. Q. Okay. So are are you saying that based on today's knowledge, that if a patient becomes hypothermic, that you're only going to see a 30-percent reduction or or warming is only going to reduce those patients strike that maintaining normothermia in colorectal patients will only reduce the infection rate by approximately 30 percent or so? A. Absolutely. I would
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What where is it? I don't know. Most likely the majority were superficial. Yeah. Q. Would you agree with me that of the 200 patients, the ones that got infection, they were mostly superficial infections with few clinical consequences? A. I would agree with that, yes. Q. Okay. And would you agree with me today that if you if you looked at what was considered hypothermia today with colorectal surgery, you're expecting, instead of a three-fold reduction in infections, about 30 percent? That would be your hypothesis?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do. Q. It says, "the factor of 3 risk increase is not plausible (30 or so is is more likely)." A. Yes. Q. Do you agree with that statement? A. Absolutely. Q. Okay. So are are you saying that based on today's knowledge, that if a patient becomes hypothermic, that you're only going to see a 30-percent reduction or or warming is only going to reduce those patients strike that maintaining normothermia in colorectal patients will only reduce the infection rate by approximately 30 percent or so? A. Absolutely. I would Yes.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What where is it? I don't know. Most likely the majority were superficial. Yeah. Q. Would you agree with me that of the 200 patients, the ones that got infection, they were mostly superficial infections with few clinical consequences? A. I would agree with that, yes. Q. Okay. And would you agree with me today that if you if you looked at what was considered hypothermia today with colorectal surgery, you're expecting, instead of a three-fold reduction in infections, about 30 percent? That would be your hypothesis? A. Yeah, it might be.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do. Q. It says, "the factor of 3 risk increase is not plausible (30 or so is is more likely)." A. Yes. Q. Do you agree with that statement? A. Absolutely. Q. Okay. So are are you saying that based on today's knowledge, that if a patient becomes hypothermic, that you're only going to see a 30-percent reduction or or warming is only going to reduce those patients strike that maintaining normothermia in colorectal patients will only reduce the infection rate by approximately 30 percent or so? A. Absolutely. I would Yes. Q. So what is wrong with the Kurz paper then?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What where is it? I don't know. Most likely the majority were superficial. Yeah. Q. Would you agree with me that of the 200 patients, the ones that got infection, they were mostly superficial infections with few clinical consequences? A. I would agree with that, yes. Q. Okay. And would you agree with me today that if you if you looked at what was considered hypothermia today with colorectal surgery, you're expecting, instead of a three-fold reduction in infections, about 30 percent? That would be your hypothesis? A. Yeah, it might be. Q. Do you recall informing that to 3M during an	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do. Q. It says, "the factor of 3 risk increase is not plausible (30 or so is is more likely)." A. Yes. Q. Do you agree with that statement? A. Absolutely. Q. Okay. So are are you saying that based on today's knowledge, that if a patient becomes hypothermic, that you're only going to see a 30-percent reduction or or warming is only going to reduce those patients strike that maintaining normothermia in colorectal patients will only reduce the infection rate by approximately 30 percent or so? A. Absolutely. I would Yes. Q. So what is wrong with the Kurz paper then? Why is why is three-fold incorrect today?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What where is it? I don't know. Most likely the majority were superficial. Yeah. Q. Would you agree with me that of the 200 patients, the ones that got infection, they were mostly superficial infections with few clinical consequences? A. I would agree with that, yes. Q. Okay. And would you agree with me today that if you if you looked at what was considered hypothermia today with colorectal surgery, you're expecting, instead of a three-fold reduction in infections, about 30 percent? That would be your hypothesis? A. Yeah, it might be. Q. Do you recall informing that to 3M during an advisory meeting?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do. Q. It says, "the factor of 3 risk increase is not plausible (30 or so is is more likely)." A. Yes. Q. Do you agree with that statement? A. Absolutely. Q. Okay. So are are you saying that based on today's knowledge, that if a patient becomes hypothermic, that you're only going to see a 30-percent reduction or or warming is only going to reduce those patients strike that maintaining normothermia in colorectal patients will only reduce the infection rate by approximately 30 percent or so? A. Absolutely. I would Yes. Q. So what is wrong with the Kurz paper then? Why is why is three-fold incorrect today? A. It probably is a very small study.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What where is it? I don't know. Most likely the majority were superficial. Yeah. Q. Would you agree with me that of the 200 patients, the ones that got infection, they were mostly superficial infections with few clinical consequences? A. I would agree with that, yes. Q. Okay. And would you agree with me today that if you if you looked at what was considered hypothermia today with colorectal surgery, you're expecting, instead of a three-fold reduction in infections, about 30 percent? That would be your hypothesis? A. Yeah, it might be. Q. Do you recall informing that to 3M during an advisory meeting? A. I don't recall it, but it sounds as	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do. Q. It says, "the factor of 3 risk increase is not plausible (30 or so is is more likely)." A. Yes. Q. Do you agree with that statement? A. Absolutely. Q. Okay. So are are you saying that based on today's knowledge, that if a patient becomes hypothermic, that you're only going to see a 30-percent reduction or or warming is only going to reduce those patients strike that maintaining normothermia in colorectal patients will only reduce the infection rate by approximately 30 percent or so? A. Absolutely. I would Yes. Q. So what is wrong with the Kurz paper then? Why is why is three-fold incorrect today? A. It probably is a very small study. Q. Okay. And you never looked at deep-tissue
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What where is it? I don't know. Most likely the majority were superficial. Yeah. Q. Would you agree with me that of the 200 patients, the ones that got infection, they were mostly superficial infections with few clinical consequences? A. I would agree with that, yes. Q. Okay. And would you agree with me today that if you if you looked at what was considered hypothermia today with colorectal surgery, you're expecting, instead of a three-fold reduction in infections, about 30 percent? That would be your hypothesis? A. Yeah, it might be. Q. Do you recall informing that to 3M during an advisory meeting? A. I don't recall it, but it sounds as something like I could have said.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do. Q. It says, "the factor of 3 risk increase is not plausible (30 or so is is more likely)." A. Yes. Q. Do you agree with that statement? A. Absolutely. Q. Okay. So are are you saying that based on today's knowledge, that if a patient becomes hypothermic, that you're only going to see a 30-percent reduction or or warming is only going to reduce those patients strike that maintaining normothermia in colorectal patients will only reduce the infection rate by approximately 30 percent or so? A. Absolutely. I would Yes. Q. So what is wrong with the Kurz paper then? Why is why is three-fold incorrect today? A. It probably is a very small study. Q. Okay. And you never looked at deep-tissue infection, just general infections; correct?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What where is it? I don't know. Most likely the majority were superficial. Yeah. Q. Would you agree with me that of the 200 patients, the ones that got infection, they were mostly superficial infections with few clinical consequences? A. I would agree with that, yes. Q. Okay. And would you agree with me today that if you if you looked at what was considered hypothermia today with colorectal surgery, you're expecting, instead of a three-fold reduction in infections, about 30 percent? That would be your hypothesis? A. Yeah, it might be. Q. Do you recall informing that to 3M during an advisory meeting? A. I don't recall it, but it sounds as something like I could have said. MR. ASSAAD: Exhibit No. 218, please.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do. Q. It says, "the factor of 3 risk increase is not plausible (30 or so is is more likely)." A. Yes. Q. Do you agree with that statement? A. Absolutely. Q. Okay. So are are you saying that based on today's knowledge, that if a patient becomes hypothermic, that you're only going to see a 30-percent reduction or or warming is only going to reduce those patients strike that maintaining normothermia in colorectal patients will only reduce the infection rate by approximately 30 percent or so? A. Absolutely. I would Yes. Q. So what is wrong with the Kurz paper then? Why is why is three-fold incorrect today? A. It probably is a very small study. Q. Okay. And you never looked at deep-tissue infection, just general infections; correct? A. No. Deep tissue were looked at. It's only
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What where is it? I don't know. Most likely the majority were superficial. Yeah. Q. Would you agree with me that of the 200 patients, the ones that got infection, they were mostly superficial infections with few clinical consequences? A. I would agree with that, yes. Q. Okay. And would you agree with me today that if you if you looked at what was considered hypothermia today with colorectal surgery, you're expecting, instead of a three-fold reduction in infections, about 30 percent? That would be your hypothesis? A. Yeah, it might be. Q. Do you recall informing that to 3M during an advisory meeting? A. I don't recall it, but it sounds as something like I could have said.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	tissue/organ SSIs)" Did I read that correctly? A. Yes, you do. Q. It says, "the factor of 3 risk increase is not plausible (30 or so is is more likely)." A. Yes. Q. Do you agree with that statement? A. Absolutely. Q. Okay. So are are you saying that based on today's knowledge, that if a patient becomes hypothermic, that you're only going to see a 30-percent reduction or or warming is only going to reduce those patients strike that maintaining normothermia in colorectal patients will only reduce the infection rate by approximately 30 percent or so? A. Absolutely. I would Yes. Q. So what is wrong with the Kurz paper then? Why is why is three-fold incorrect today? A. It probably is a very small study. Q. Okay. And you never looked at deep-tissue infection, just general infections; correct?

29 (Pages 113 to 116)

	Page 117		Page 119
1	Q. Okay. Do you know how many there were?	1	A. Yes.
2	A. No, I don't.	2	Q. They use the Bair Hugger; correct?
3	Q. Is there any way to find out?	3	A. Yes.
4	A. I doubt after 20 years.	4	Q. They promote the Bair Hugger in orthopedic
5	Q. Is the data still available?	5	surgery; correct?
6	A. I doubt it.	6	A. Yeah.
. 7	Q. Okay. So if there were any, it would be	7	Q. Okay. Have you ever told them that there's
8	very few.	8	no evidence that 3M
9	A. Yes, absolutely.	9	Or have you ever told them that there's
10	Q. Okay. If there were any. You're not even	10 -	evidence that maintaining normothermia reduces the
11	sure there were any at all.	11	incidence of periprosthetic joint infection?
12	A. I don't.	12	A. No.
13	Q. Okay. So sitting here today, there is no	13	Q. Have you ever informed them that there is no
14	evidence for you to offer the opinion that maintaining	14	evidence that periprosthetic maintaining
15	normothermia reduces the incidence of deep-tissue	15	normothermia reduces the incidence of periprosthetic
16	infection.	16	joint infection?
17	MR. GORDON: Object to the form of the	17	A. Yes.
18	question, also lack of foundation.	18	Q. You have told them that?
19	A. I wouldn't phrase it that way.	19	A. Yeah, of course. My paper says at the end
20	Q. How would you phrase it?	20	that or it should say that every every
21	A. I'm not sure. I'm not	21	patient
22	That's one I would have to think about. I	22	Advice always only applies to the patient
23	don't know.	23	population tested.
24	Q. Well is there any evidence	24	Q. I understand that. But you
25	A. I just don't know.	25	A. I can't advise anybody that it would work in
	•		
	Page 118		Page 120
1	Q. Is there any evidence of any research that	1	eye surgery now or in orthopedic. I don't know.
. 2	you've done or read that indicates that maintaining	2	Q. Well what can you advise people then, that
3	normothermia reduces the incidence of a deep-tissue	1 3	it only works in colorectal?
4	infection?	4 .	A. Strictly spoken, yes.
5	A. I doubt there is,	5	Q. Okay. But you're
6	Q. Okay.	6	A. For that indication.
7	A but I don't know.	7	Q. For what indication?
8	Q. And you agree with me that there's no	8	A. Infection.
9	evidence in the literature that you're aware of that	9	Q. Okay.
10	indicates that maintaining normothermia reduces the	10	A. Might be different for other indications.
1:1	incidence of a periprosthetic joint infection.	.11	Q. Okay. Let's talk about infection. So
12	MR. GORDON: Object to the form of the	12	you've never
13	question, also lack of foundation.	13	Have you ever advised 3M that there's no
14	A. So you're saying no there's no evidence	14	study that supports or that that you can advise
15	that normothermia decreases the incidence of	15	them that forced-air warming and maintaining normo
16	Q. Maintaining normo	16	to maintain normothermia is required for
17	Of periprosthetic joint infections.	17	periprosthetic or for orthopedic surgeries to
18	MS. DIFRANCO: Are you asking what she's	18	reduce periprosthetic joint infection?
19	done or	19	A. Your question is complicated. So I have
20	I mean you're getting into some expert	20	not
21	testimony here.	21	Yeah, it's hard for me to understand the
22	MR. ASSAAD: Well I'm not, and I	22	question. I think I didn't advise them to
23	If you want me to lay more foundation, I	23	specifically use it for decrease in periprosthetic
24	will I can. Fine, I'll lay foundation.	24	infections.
25	Q. You advised for 3M; correct?	25	Q. Okay. You're aware that Bair Hugger or

30 (Pages 117 to 120)

	Page 121		Page 123
1	3M and Arizant have marketed the Bair Hugger for all	1	A. Yes, I did.
2	surgeries	2	Q. Okay. And you're basing it off this one
3	A. Yes.	3	study that was done in 1996; correct?
4	Q that last longer than an hour.	4	A. No.
5	A. Yes.	5	Q. What else are you basing it on?
6	Q. Okay. And you're on the advisory panel for	6	A. Not correct. We based it off on two or
7	them; correct?	7	some studies that looked at blood loss and transfusion
8	A. Uh-huh, yes.	8	requirements back then. We based it off on a study
9	Q. And so is Dr. Sessler, for a longer time	9	that showed decreased myocardial injury, although a
10	than you have.	10	very weak study
11 -	A. Yes.	11	Q. Is that the Frank study?
12	Q. Okay. And are you saying, sitting here	12	A. That was the Frank study.
13	today, that the only advice that you could give is	13	So actually, I'm not basing it on this any
14	that that that maintaining normothermia in	14	more, but we used to. We base it off on studies that
1.5	colorectal surgeries reduces the incidence of	15	show that drugs are metabolized differently with
16	infection?	16	hypothermia. So it's not only one study
17	A. That's the scientific advice.	17	Q. Okay.
18	Q. Okay.	18	A we base this on.
19	A. My clinical interpretation might be slightly	19	Q. But with respect to reducing infections
20	different.	20	A. That's the only study we have.
21	Q. How is it different?	21	Q. Okay. And you also looked at length of stay
22	A. It's that that if it does help in a	22	in this in this in in this article; correct?
23	certain patient population, it might it's also not	23	A. In this particular study, yes.
24	proven do the same thing in others, and I guess	24	Q. Okay. And after, I guess, other one came
25	that's why	25	in in 19 in 2006. So after 19 years, the
	Page 122		Page 124
1	Q. It may.	1	information has changed and now you cannot say from a
2	A. It may.	2	scientific statistical significance that maintaining
3	Q. And it may not.	3	
4	A T 314 1	1	normothermia has any effect on the length of stay in
1	A. I don't know.	4	normothermia has any effect on the length of stay in the hospital.
5	And it may not.	4 5	the hospital. A. No. But it's all the very different
6	And it may not. Q. Okay. And unless you and	5 6	the hospital. A. No. But it's all the very different conditions. So the first study, first of all,
	And it may not. Q. Okay. And unless you and And sitting here today, you don't understand	5	the hospital. A. No. But it's all the very different conditions. So the first study, first of all, patients were in the hospital forever, so it's easy to
6	And it may not. Q. Okay. And unless you and And sitting here today, you don't understand the host defense of a a a an individual that	5 6	the hospital. A. No. But it's all the very different conditions. So the first study, first of all, patients were in the hospital forever, so it's easy to see a difference. If you look at the duration of
6 7	And it may not. Q. Okay. And unless you and And sitting here today, you don't understand the host defense of a a a an individual that has that has bacteria that lands on an implant	5 6 7 8 9	the hospital. A. No. But it's all the very different conditions. So the first study, first of all, patients were in the hospital forever, so it's easy to see a difference. If you look at the duration of hospitalization, I think it was 12 or 14 days 25 years
6 7 8	And it may not. Q. Okay. And unless you and And sitting here today, you don't understand the host defense of a a a an individual that	5 6 7 8	the hospital. A. No. But it's all the very different conditions. So the first study, first of all, patients were in the hospital forever, so it's easy to see a difference. If you look at the duration of hospitalization, I think it was 12 or 14 days 25 years ago, and now it's five days, so it's much harder to
6 7 8 9 10 11	And it may not. Q. Okay. And unless you and And sitting here today, you don't understand the host defense of a a a an individual that has that has bacteria that lands on an implant	5 6 7 8 9 10 11	the hospital. A. No. But it's all the very different conditions. So the first study, first of all, patients were in the hospital forever, so it's easy to see a difference. If you look at the duration of hospitalization, I think it was 12 or 14 days 25 years ago, and now it's five days, so it's much harder to show a difference even with hundred times as many
6 7 8 9 10 11 12	And it may not. Q. Okay. And unless you and And sitting here today, you don't understand the host defense of a a a an individual that has that has bacteria that lands on an implant during a total knee or total hip arthroplasty; correct? A. That is correct.	5 6 7 8 9 10 11 12	the hospital. A. No. But it's all the very different conditions. So the first study, first of all, patients were in the hospital forever, so it's easy to see a difference. If you look at the duration of hospitalization, I think it was 12 or 14 days 25 years ago, and now it's five days, so it's much harder to show a difference even with hundred times as many patients. And what you actually do see in the
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	And it may not. Q. Okay. And unless you and And sitting here today, you don't understand the host defense of a a a an individual that has that has bacteria that lands on an implant during a total knee or total hip arthroplasty; correct? A. That is correct. MR. GORDON: Object to the form of the question. Q. All right. Sitting here today, do you know whether or not hypothermia has any impact on the host defense of an individual that that's implant was contaminated during the perioperative period with bacteria? A. I don't know. Q. You've gone around the world promoting	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	the hospital. A. No. But it's all the very different conditions. So the first study, first of all, patients were in the hospital forever, so it's easy to see a difference. If you look at the duration of hospitalization, I think it was 12 or 14 days 25 years ago, and now it's five days, so it's much harder to show a difference even with hundred times as many patients. And what you actually do see in the retrospective study is that if the temperature gets low enough, it starts to have a difference, which actually is doesn't contradict what we said before. Q. What do you mean when you look if the temperature gets low enough? A. While in the retrospective and the other The large thing is, of course, that retrospective studies only show an association and never a causal relationship. So which study is stronger, which weaker, is is to be discussed. If
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	And it may not. Q. Okay. And unless you and And sitting here today, you don't understand the host defense of a a a an individual that has that has bacteria that lands on an implant during a total knee or total hip arthroplasty; correct? A. That is correct. MR. GORDON: Object to the form of the question. Q. All right. Sitting here today, do you know whether or not hypothermia has any impact on the host defense of an individual that that's implant was contaminated during the perioperative period with bacteria? A. I don't know. Q. You've gone around the world promoting maintaining normothermia; correct?	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	the hospital. A. No. But it's all the very different conditions. So the first study, first of all, patients were in the hospital forever, so it's easy to see a difference. If you look at the duration of hospitalization, I think it was 12 or 14 days 25 years ago, and now it's five days, so it's much harder to show a difference even with hundred times as many patients. And what you actually do see in the retrospective study is that if the temperature gets low enough, it starts to have a difference, which actually is — doesn't contradict what we said before. Q. What do you mean when you look if the temperature gets low enough? A. While in the retrospective — and the other — The large thing is, of course, that retrospective studies only show an association and never a causal relationship. So which study is
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	And it may not. Q. Okay. And unless you and And sitting here today, you don't understand the host defense of a a a an individual that has that has bacteria that lands on an implant during a total knee or total hip arthroplasty; correct? A. That is correct. MR. GORDON: Object to the form of the question. Q. All right. Sitting here today, do you know whether or not hypothermia has any impact on the host defense of an individual that that's implant was contaminated during the perioperative period with bacteria? A. I don't know. Q. You've gone around the world promoting maintaining normothermia; correct? A. Yes.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	the hospital. A. No. But it's all the very different conditions. So the first study, first of all, patients were in the hospital forever, so it's easy to see a difference. If you look at the duration of hospitalization, I think it was 12 or 14 days 25 years ago, and now it's five days, so it's much harder to show a difference even with hundred times as many patients. And what you actually do see in the retrospective study is that if the temperature gets low enough, it starts to have a difference, which actually is doesn't contradict what we said before. Q. What do you mean when you look if the temperature gets low enough? A. While in the retrospective and the other The large thing is, of course, that retrospective studies only show an association and never a causal relationship. So which study is stronger, which weaker, is is to be discussed. If

31 (Pages 121 to 124)

	Page 125		Page 127
1	of me, but we looked, as you mentioned before, at	1	it
2	depth and duration, and if you get very deep and long,	2	To negate that, yes.
3	I think you would see a a a relationship which	3	Q. Okay.
4	is core temperatures, which we nowadays don't see any	4	A. Sorry. Yes.
- 5	more, but we used to see many years ago.	5	Q. Okay. And even here it says, "In contrast,
6	(Discussion off the stenographic record.)	6	it is well established that prewarming reduces
7	(Exhibit 243 was marked for	7	redistribution hypothermia by warming peripheral
8	identification.)	8	tissues to nearly core temperature."
9	A. Let's see. Should be all the way back.	9	A. Correct.
10	So you have a graph on Bate page 283. So	10	Q. "Without thermal gradient, the second Law of
11	where you have the two probabilities	11	Thermodynamics specifies that there can be no flow of
12	I guess the left-hand side is the	12	heat and thus no redistribution hypothermia."
13	transfusion data. Is that correct?	13	A. Uh-huh.
14	Q. Yes.	14	Q. Correct?
15	A. And the right-hand side should be duration	15	A. Yes.
16	of hospitalization. So you do see that both the	16	Q. Okay. And just going back, that's kind of
17	the curves are quite similar, they just happen at	17	what Mercury Biomed is trying to do in a way.
18	different temperature ranges. So if you would get low	18	A. Yeah. Not only pre
. 19	enough with this one, with the right one, which is	19	Yes.
20	something we don't see that commonly any more, you	20	Q. Uh-huh.
21	would probably see an effect.	21	A. A little bit, yes.
22	Q. Well for example, let let's take a	22	Q. And also to increase vasoconstriction so you
23	surgery of two hours. Not a colorectal, but a	23	could have the heat flow and create heat from the
24	two-hour surgery.	24	extremities and can bring it back to the core.
25	A. Uh-huh.	25	A. Yes, exactly.
1 2	Q. I mean what what do you usually see for degree hours on on a	1 2	Q. And is it true that even with warming, any type of warming, that a patient still becomes
3	A. Nowadays?	3	
4	· ·		hypothermic within the first hour of surgery?
-1	() Veah	1	hypothermic within the first hour of surgery?
5	Q. Yeah.	4	A. Yes. Still is some redistribution
5 6	A. One degree. Time	4 5	A. Yes. Still is some redistribution hypothermia, it's correct.
6	A. One degree. Time I'm not sure what the time-weighted average	4 5 6	A. Yes. Still is some redistribution hypothermia, it's correct. Q. Okay. Unless there's prewarming.
6 7	A. One degree. Time I'm not sure what the time-weighted average would be. Not much.	4 5 6 7	 A. Yes. Still is some redistribution hypothermia, it's correct. Q. Okay. Unless there's prewarming. A. Even with prewarming. Then it's minimal.
6 7 8	A. One degree. Time I'm not sure what the time-weighted average would be. Not much. Q. Uh-huh. Probably	4 5 6 7 8	 A. Yes. Still is some redistribution hypothermia, it's correct. Q. Okay. Unless there's prewarming. A. Even with prewarming. Then it's minimal. Yes.
6 7 8 9	 A. One degree. Time I'm not sure what the time-weighted average would be. Not much. Q. Uh-huh. Probably A. Not much. 	4 5 6 7 8 9	 A. Yes. Still is some redistribution hypothermia, it's correct. Q. Okay. Unless there's prewarming. A. Even with prewarming. Then it's minimal. Yes. Q. Okay. And is the same is is the
6 7 8 9 10	 A. One degree. Time I'm not sure what the time-weighted average would be. Not much. Q. Uh-huh. Probably A. Not much. Q. It wouldn't increase the length of stay or 	4 5 6 7 8 9	 A. Yes. Still is some redistribution hypothermia, it's correct. Q. Okay. Unless there's prewarming. A. Even with prewarming. Then it's minimal. Yes. Q. Okay. And is the same is is the Is the curve the same, with regard to the
6 7 8 9 10	 A. One degree. Time I'm not sure what the time-weighted average would be. Not much. Q. Uh-huh. Probably A. Not much. Q. It wouldn't increase the length of stay or transfusion rates. I mean it wouldn't increase the 	4 5 6 7 8 9 10	 A. Yes. Still is some redistribution hypothermia, it's correct. Q. Okay. Unless there's prewarming. A. Even with prewarming. Then it's minimal. Yes. Q. Okay. And is the same is is the Is the curve the same, with regard to the drop in core temperature in the first hour, the same
6 7 8 9 10 11	A. One degree. Time I'm not sure what the time-weighted average would be. Not much. Q. Uh-huh. Probably A. Not much. Q. It wouldn't increase the length of stay or transfusion rates. I mean it wouldn't increase the transfusion rates.	4 5 6 7 8 9 10 11	 A. Yes. Still is some redistribution hypothermia, it's correct. Q. Okay. Unless there's prewarming. A. Even with prewarming. Then it's minimal. Yes. Q. Okay. And is the same is is the Is the curve the same, with regard to the drop in core temperature in the first hour, the same whether or not the patient is is warmed?
6 7 8 9 10 11 12	A. One degree. Time I'm not sure what the time-weighted average would be. Not much. Q. Uh-huh. Probably A. Not much. Q. It wouldn't increase the length of stay or transfusion rates. I mean it wouldn't increase the transfusion rates. A. Nowadays, I don't think so.	4 5 6 7 8 9 10 11 12	 A. Yes. Still is some redistribution hypothermia, it's correct. Q. Okay. Unless there's prewarming. A. Even with prewarming. Then it's minimal. Yes. Q. Okay. And is the same is is the Is the curve the same, with regard to the drop in core temperature in the first hour, the same whether or not the patient is is warmed? A. Intraoperatively.
6 7 8 9 10 11 12 13	A. One degree. Time I'm not sure what the time-weighted average would be. Not much. Q. Uh-huh. Probably A. Not much. Q. It wouldn't increase the length of stay or transfusion rates. I mean it wouldn't increase the transfusion rates. A. Nowadays, I don't think so. Q. Okay. Going to page 282, first main	4 5 6 7 8 9 10 11 12 13	 A. Yes. Still is some redistribution hypothermia, it's correct. Q. Okay. Unless there's prewarming. A. Even with prewarming. Then it's minimal. Yes. Q. Okay. And is the same is is the Is the curve the same, with regard to the drop in core temperature in the first hour, the same whether or not the patient is is warmed? A. Intraoperatively. Q. Yes.
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	Page 129		Page 131
1	you looked at at at their drop in in in	1	A. I'm not quite a statistician, but I can try.
2	core temperature over	2	So I think in the left-hand column you have
3	A. Yeah, it's about .6 to 1 degree, yes.	3	the area under the curve below 37 degrees core
4	Q. Okay. So the first hour.	4	temperature in what we explained before, degrees times
5	A. About, yeah.	5.	hour, and what you see, that the adjusted odds ratio
6	Q. Okay. And the difference, my understanding	6	to receive an intraoperative transfusion with
7	is when you have warming, the core temperature begins	7	increased area under 37 significantly increases, so it
8	to increase, and if you have no warming, it continues	8	almost doubles from 1.34 to 2.02, so it is a very,
9	to decrease.	9	very strong effect. So the deeper and the longer the
10	A. Until it plateaus, yes.	10	hypothermia, the more transfusions.
11	Q. So about 34.5 degrees, give or take the type	11	Q. And we don't have to talk about the duration
12	of patient.	12	of hospitalization because that's statistically
13	A. Uh-huh.	13	insignificant; correct?
14	Q. Okay. Yes?	14	A. Right.
15	A. Yes.	15	Q. Let me ask you a question. The reference to
16	Q. Okay. So if a surgery is lasting one hour	16	36 degrees as a reference point as
17	or less, would you agree with me that maintaining	17	A. I think we used 37 here.
18	normothermia has no effect on the incidence of	18	Q. Well it's average under area under 37 in
19	infection?	19	degree hours.
20	A. No. I don't think	20	A. Yeah.
21	I think I don't agree with your phrasing	21	Q. So to get to the reference of where it's
22	because you	22	under one, that's
23	Q. Let let me	23	A. Thirty-six.
24	A you can't not maintain normothermia.	24	Q 36 degrees.
25	Q. Okay. Okay. You're right. It was a	25	A. Yeah.
	Page 130	1.	Page 132
		1	
1	Would you agree with me that within	1	Q. Why, when you're at thirty like .25
1 2	within the first hour of a surgery, patient warming	1 2	degree hours, okay, is your risk higher than 36
	within the first hour of a surgery, patient warming has no effect on the incidence of infection, based on	1	degree hours, okay, is your risk higher than 36 degrees when you're not hypothermic for a transfusion?
2	within the first hour of a surgery, patient warming has no effect on the incidence of infection, based on your research?	2	degree hours, okay, is your risk higher than 36
2	within the first hour of a surgery, patient warming has no effect on the incidence of infection, based on	2 3	degree hours, okay, is your risk higher than 36 degrees when you're not hypothermic for a transfusion? A. It's not higher. It's almost a linear decrease.
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	Page 133	,	Page 135
1	shorter period of time, you have a higher risk of a	1	A. We do work together a lot, but not on not
2	transfusion, which doesn't make any sense.	2	exactly all topics.
3	A. No, it doesn't. And that's why I think if	. 3	Q. Okay. Are you aware of any comments by the
4	you are at the higher temp so you're at the lower	4	CDC with respect to blowing air devices that blow
5	temperature	5	air in the operating room?
6	I need to think about it,	6	A. No, I'm not.
7	Q. Okay.	7	Q. Okay. Are you familiar with any issues
8	A obviously. But you're right.	8	with
9	Q. So so in your experience doing total knee	9	Do you know what a heater/cooler unit is
1.0	and total hip implant surgeries, how long do they	10	that's used in cardiac surgery?
11	usually last for?	11	A. I assume it's something that can heat and
12	A. Here at the clinic, two and a half to three	12	cool.
13	hours outside.	13	Q. Yeah. Are you familiar with that device?
14	Q. For hip or knee, for both?	14	A. Not with that specific one, but I've seen it
15	A. I would say for almost both. Hip would be	15	before.
16	longer. I think in the real world they last about	16	Q. Are you familiar with the issues with the
17	half an hour, 45 minutes.	17	Sorin heater/cool unit and the causing of infections
18	Q. Why do they last longer here?	18	in the operating room?
19	A. Because we are a teaching institution.	19	A. No.
20	Q. Okay. All right.	20	Q. Now it's it's my understanding that,
21	MR. ASSAAD: Want to take a break? I think	21	based on lectures that I've seen that you did that are
22	this is a good time for a break.	22	on YouTube, that the modality of of which way a
23	THE REPORTER: Off the record, please.	23	patient is warmed is insignificant to you, which
24	(Recess taken.)	24	which which what whatever convention it uses;
25	BY MS. DIFRANCO:	25	correct?
	Page 134		Page 136
	i age 154		
-	O Producto continuo		
1	Q. Ready to continue?	1	A. Yes.
2	A. Yes.	2	A. Yes.Q. And based on research that I've read, you
2 3	A. Yes. Q. Do you have	3	A. Yes.Q. And based on research that I've read, you agree with me that conductive warming using maybe
2 3 4	A. Yes.Q. Do you haveYou have you have no expertise in with	2 3 4	A. Yes. Q. And based on research that I've read, you agree with me that conductive warming using maybe resistive polymers is just as effective as forced-air
2 3 4 5	 A. Yes. Q. Do you have You have you have no expertise in with respect to the types of ventilation used in an OR; 	2 3 4 5	A. Yes. Q. And based on research that I've read, you agree with me that conductive warming using maybe resistive polymers is just as effective as forced-air warming.
2 3 4 5 6	A. Yes. Q. Do you have You have you have no expertise in with respect to the types of ventilation used in an OR; correct? Things like laminar, unidirectional or	2 3 4 5 6	 A. Yes. Q. And based on research that I've read, you agree with me that conductive warming using maybe resistive polymers is just as effective as forced-air warming. A. I think I would agree, yes.
2 3 4 5 6 7	A. Yes. Q. Do you have You have you have no expertise in with respect to the types of ventilation used in an OR; correct? Things like laminar, unidirectional or conventional?	2 3 4 5 6 7	 A. Yes. Q. And based on research that I've read, you agree with me that conductive warming using maybe resistive polymers is just as effective as forced-air warming. A. I think I would agree, yes. Q. You think you would agree or would you
2 3 4 5 6 7 8	 A. Yes. Q. Do you have You have you have no expertise in with respect to the types of ventilation used in an OR; correct? Things like laminar, unidirectional or conventional? A. Oh, sorry. No, no. 	2 3 4 5 6 7 8	 A. Yes. Q. And based on research that I've read, you agree with me that conductive warming using maybe resistive polymers is just as effective as forced-air warming. A. I think I would agree, yes. Q. You think you would agree or would you agree?
2 3 4 5 6 7 8 9	 A. Yes. Q. Do you have You have you have no expertise in with respect to the types of ventilation used in an OR; correct? Things like laminar, unidirectional or conventional? A. Oh, sorry. No, no. Q. Okay. Are you familiar with the Daniel 	2 3 4 5 6 7 8	 A. Yes. Q. And based on research that I've read, you agree with me that conductive warming using maybe resistive polymers is just as effective as forced-air warming. A. I think I would agree, yes. Q. You think you would agree or would you agree? A. I agree. Sorry, I was thinking further.
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2 3 4 5 6 7 8 9 10	A. Yes. Q. Do you have You have you have no expertise in with respect to the types of ventilation used in an OR; correct? Things like laminar, unidirectional or conventional? A. Oh, sorry. No, no. Q. Okay. Are you familiar with the Daniel Sessler article of 2011, which he did a study in respect to particle counts and laminar flow?	2 3 4 5 6 7 8 9 10	A. Yes. Q. And based on research that I've read, you agree with me that conductive warming using maybe resistive polymers is just as effective as forced-air warming. A. I think I would agree, yes. Q. You think you would agree or would you agree? A. I agree. Sorry, I was thinking further. I I agree in regards to efficiency. Q. What do you mean by "efficiency?"
2 3 4 5 6 7 8 9 10 11	A. Yes. Q. Do you have You have you have no expertise in with respect to the types of ventilation used in an OR; correct? Things like laminar, unidirectional or conventional? A. Oh, sorry. No, no. Q. Okay. Are you familiar with the Daniel Sessler article of 2011, which he did a study in respect to particle counts and laminar flow? A. I'm not.	2 3 4 5 6 7 8 9 10 11	A. Yes. Q. And based on research that I've read, you agree with me that conductive warming using maybe resistive polymers is just as effective as forced-air warming. A. I think I would agree, yes. Q. You think you would agree or would you agree? A. I agree. Sorry, I was thinking further. I I agree in regards to efficiency. Q. What do you mean by "efficiency?" A. So I think heat transfer is similar. Cost
2 3 4 5 6 7 8 9 10 11 12 13	 A. Yes. Q. Do you have You have you have no expertise in with respect to the types of ventilation used in an OR; correct? Things like laminar, unidirectional or conventional? A. Oh, sorry. No, no. Q. Okay. Are you familiar with the Daniel Sessler article of 2011, which he did a study in respect to particle counts and laminar flow? A. I'm not. Q. Okay. Did you ever have any discussions 	2 3 4 5 6 7 8 9 10 11 12 13	A. Yes. Q. And based on research that I've read, you agree with me that conductive warming using maybe resistive polymers is just as effective as forced-air warming. A. I think I would agree, yes. Q. You think you would agree or would you agree? A. I agree. Sorry, I was thinking further. I I agree in regards to efficiency. Q. What do you mean by "efficiency?" A. So I think heat transfer is similar. Cost for most of these devices is higher.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. Q. Do you have You have you have no expertise in with respect to the types of ventilation used in an OR; correct? Things like laminar, unidirectional or conventional? A. Oh, sorry. No, no. Q. Okay. Are you familiar with the Daniel Sessler article of 2011, which he did a study in respect to particle counts and laminar flow? A. I'm not. Q. Okay. Did you ever have any discussions with him about that study? A. No. Q. Okay. Were you aware that he he did a study for a favor for 3M or authored a study as a favor for 3M back in 2011 that was published? A. I don't think so. Q. Okay. A. I I also don't think I was part of it. Q. I I understand you were not part of that.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. Q. And based on research that I've read, you agree with me that conductive warming using maybe resistive polymers is just as effective as forced-air warming. A. I think I would agree, yes. Q. You think you would agree or would you agree? A. I agree. Sorry, I was thinking further. I I agree in regards to efficiency. Q. What do you mean by "efficiency?" A. So I think heat transfer is similar. Cost for most of these devices is higher. Q. Cost. Okay. (Exhibit 244 was marked for identification.) BY MR. ASSAAD: Q. Dr. Kurz, what's been marked as Exhibit 244 is a publication in Anesthesia & Analgesia titled "Resistive-Polymer Versus Forced-Air Warming: Comparable Efficacy in Orthopedic Patients." Are you familiar with this article?

34 (Pages 133 to 136)

	Page 137		Page 139
1	A. Yes, I am.	1	triple is correct for that particular paper or what we
2	Q. Okay. What was your contribution to this	2	cite here. Whether the effect size is the same
3	article?	3	nowadays, I don't know.
4	A. I'm just thinking. I think at that point in	4	Q. But would you agree with me that, as you
5	time I was the chair of the Department of Anesthesia	5	stated previously, the third the triple the
6	at this and this is a group of my fellows who did	6	reduction by three times only applies to colorectal
7	this study, so I probably corrected and had input in	7	surgery, that that's where the evidence is; correct?
8	the methods.	8	A. Absolutely.
9	Q. And and you agree with the result of this	9.	MR. GORDON: Object.
10	study?	10	Q. But it doesn't say that here; does it?
11	A. Yeah. If my name is on there, yes.	11	A. No, but it cites the paper.
12	Q. Okay. I just want to go over certain parts	12	Q. I understand that. But a person reading
13	of that's written in this. And you have you	13	this, wouldn't he be misled that this applies to all
i 4	strike that.	14	surgeries?
15	*Did you have the opportunity to edit this	15	MR. GORDON: Object to the form of the
16	study before it went to publication?	16	question, lack of foundation.
17	A. I'm sure I did.	17.	A. I don't know.
18	Q. Okay. And in two thousand this is	·18 ·	Q. Okay. I mean it doesn't say anywhere here
19	published in 2010. During the time and it was	19	colorectal surgery; correct?
20	accepted for publication on November 8th, 2009.	20	A. No, it does not.
21	At the time that this study came out, were	21	Q. Okay. And in fact, nothing in this
22	you on the advisory board for 3M?	22	paragraph, with all this data, applies to the type of
23	A. I don't know.	23	surgery that there's evidence that these statements
24	Q. All right. Going to the first paragraph,	24	support; correct?
25	about the second or third sentence down, it starts,	25	A. Oh, absolutely it does. It's the first
	Page 138		Page 140
1	"Even mild hypothermia" Do you see that?	1	The first part applies to colorectal, the
2	A. Second sentence	2	second part to orthopedic, last part I cannot
3	Q. Seventh line down.	3	remember.
4	A. "Even mild hypothermia" Yes.	4	Q. And the orthopedic reference is, I think,
5	Q. Says, "Even mild hypothermia triples the	5	Schmid or
6	incidence of post-operative wound infection and	6	A. It's Schmid and
7	increases the hospital length of stay"	7	Q. Hertz Kurz.
8	A. Uh-huh.	8	A. No, no, I wasn't the first author on any of
9	Q "by 20 percent, increases blood loss and	9	those. It's Schmid, and there's a second one in
10	blood transfusion requirements, and increases the	10	orthopedic, Visna or ba ba ba ba.
11	incidence of cardiovascular complications and thermo	11	Schmid. I guess they only had Schmid at
12	discomfort of patients."	12	that time, yeah.
13	Did I read that correctly?	13	Q. And that that's an article in The Lancet
14	A. Yes, you did.	14	published in 1996; correct?
15	Q. Sitting here today, would I be correct that	15	A. Correct.
16	you disagree or your hypothesis is different with	16	Q. And actually, you put that down in in
17	respect to hypothermia reducing the incidence of	17	your CV as a separate category of publications, "High
18	post-operative infection by or or triples the	18	Profile Articles;" correct?
19	incidence of post-operative wound infection?	19	A. Correct.
20	A. The statement is correct.	20	Q. Okay. Along with the 1996 study of
20	Q. I understand that. But basing what	. 21	A. Correct.
21	· · · · · · · · · · · · · · · · · · ·	22	Q. Okay. So you considered those articles were
	A. Whether the effect size is the same, I	44	
2.1	A. Whether the effect size is the same, I doubt.	23	high-profile articles.
2·1 2·2			

35 (Pages 137 to 140)

	Page 141		Page 143
1	the hospital length of stay by 20 percent, as we	1	A. It's the one I was looking for in here,
2	discussed previously, based on recent studies, that's	2	but
3	questionable.	3	Q. Okay. What type of what type of
4	A. Yes, it is.	4	orthopedic surgeries?
5	Q. Okay. And increased blood loss and blood	5	A. Hip.
6	transfusion requirements, we no long want we no	6	Q. Okay. And was that around 1996?
7	want longer want to look at blood loss because	7. 7	A. Yes.
8	that's not the data is not that accurate as	8	Q. Okay. Has hip arthroplasty changed over the
9 -	compared to blood transfusions.	9	past 20 years, the way the surgery is done?
10	A. Yes.	10	A. You know what? I'm an anesthesiologist. I
11	Q. Okay.	11	guess it has.
12	A. Al although for these particular	12	Q. Okay. So you don't know one way or the
13	prospective studies, blood loss is evaluated	13	other.
14	differently than for retrospective studies. So that's	14	A. No.
15	why I said that it's unreliable for retrospective	15	Q. Okay. So sitting here today, you don't know
16	studies but not so much for prospective.	16	if if the procedure or the mechanism or or the
17	Q. And with all these studies regarding blood	17	way they do the surgery is different in 2016 as it was
18	loss, length of stay, transfusions, infections, the	18	in 1996.
19	depth of hypothermia is unknown to with with	19	A. I would hope it's different.
20	respect to the effect that the depth of hypothermia	20	Q. Okay. And in fact, the number of hip
21	would have on on these complications.	21	arthroplasties and knee arthroplasties have increased
22	A. No, that's incorrect. For all these	22	significantly over the past 20 years per year.
23	studies, the depth was very well known. They all went	23	A. I agree, yeah.
24	down to around 34.4 degrees, so they all had a very	24	Q. You write here that the resistive on
25.	large area under the curve.	25	the on the second paragraph, "This system might
	Page 142	-	Page 144
1	Q. Okay. So a patient that can be warmed with	1	have" talking about
. 2	blankets, that's at 35 degrees, 35 point between 35	۱ ،	-
2		2	A. Uh-huh.
3	and 35 degrees without active warming, we don't know	3	Q resistive polymers "This system might
4	and 35 degrees without active warming, we don't know what the effect of hypothermia would have on those		
		3	Q resistive polymers "This system might
4	what the effect of hypothermia would have on those patients with respect to infection rates, blood loss,	3 4	Q resistive polymers "This system might have some advantages compared with a forced-air
4 5	what the effect of hypothermia would have on those patients with respect to infection rates, blood loss, blood transfusions, length of stay.	3 4 5	Q resistive polymers "This system might have some advantages compared with a forced-air warming system: blankets are reusable, there is no
4 5 6	what the effect of hypothermia would have on those patients with respect to infection rates, blood loss,	3 4 5 6	Q resistive polymers "This system might have some advantages compared with a forced-air warming system: blankets are reusable, there is no air flow and thus warming can be initiated immediately
4 5 6 7	what the effect of hypothermia would have on those patients with respect to infection rates, blood loss, blood transfusions, length of stay. A. So you are asking whether a patient who has	3 4 5 6 7	Q resistive polymers "This system might have some advantages compared with a forced-air warming system: blankets are reusable, there is no air flow and thus warming can be initiated immediately after induction with anesthesia without waiting for surgical draping to be completed" Did I read that
4 5 6 7 8	what the effect of hypothermia would have on those patients with respect to infection rates, blood loss, blood transfusions, length of stay. A. So you are asking whether a patient who has a higher core temperature than 34.5 degrees would have	3 4 5 6 7 8	Q resistive polymers "This system might have some advantages compared with a forced-air warming system: blankets are reusable, there is no air flow and thus warming can be initiated immediately after induction with anesthesia without waiting for
4 5 6 7 8 9	what the effect of hypothermia would have on those patients with respect to infection rates, blood loss, blood transfusions, length of stay. A. So you are asking whether a patient who has a higher core temperature than 34.5 degrees would have a different infection rate or fewer infections.	3 4 5 6 7 8	Q resistive polymers "This system might have some advantages compared with a forced-air warming system: blankets are reusable, there is no air flow and thus warming can be initiated immediately after induction with anesthesia without waiting for surgical draping to be completed" Did I read that correctly?
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4 5 6 7 8 9 10 11	what the effect of hypothermia would have on those patients with respect to infection rates, blood loss, blood transfusions, length of stay. A. So you are asking whether a patient who has a higher core temperature than 34.5 degrees would have a different infection rate or fewer infections. Q. If any. A. I We don't know.	3 4 5 6 7 8 9 10 11	Q resistive polymers "This system might have some advantages compared with a forced-air warming system: blankets are reusable, there is no air flow and thus warming can be initiated immediately after induction with anesthesia without waiting for surgical draping to be completed" Did I read that correctly? A. Yes, you do. Q. So is it my understanding that an advantage of a resistive-polymer or conductive blanket is that
4 5 6 7 8 9 10 11 12	what the effect of hypothermia would have on those patients with respect to infection rates, blood loss, blood transfusions, length of stay. A. So you are asking whether a patient who has a higher core temperature than 34.5 degrees would have a different infection rate or fewer infections. Q. If any. A. I We don't know. Q. Okay.	3 4 5 6 7 8 9 10 11 12 13	Q resistive polymers "This system might have some advantages compared with a forced-air warming system: blankets are reusable, there is no air flow and thus warming can be initiated immediately after induction with anesthesia without waiting for surgical draping to be completed" Did I read that correctly? A. Yes, you do. Q. So is it my understanding that an advantage of a resistive-polymer or conductive blanket is that you could begin warming the patient sooner than with
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4 5 6 7 8 9 10 11 12 13 14	what the effect of hypothermia would have on those patients with respect to infection rates, blood loss, blood transfusions, length of stay. A. So you are asking whether a patient who has a higher core temperature than 34.5 degrees would have a different infection rate or fewer infections. Q. If any. A. I We don't know. Q. Okay. A. In fact, we don't know for infection. We do know for blood blood loss.	3 4 5 6 7 8 9 10 11 12 13 14 15	Q resistive polymers "This system might have some advantages compared with a forced-air warming system: blankets are reusable, there is no air flow and thus warming can be initiated immediately after induction with anesthesia without waiting for surgical draping to be completed" Did I read that correctly? A. Yes, you do. Q. So is it my understanding that an advantage of a resistive-polymer or conductive blanket is that you could begin warming the patient sooner than with forced-air warming? A. That's correct, yeah.
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36 (Pages 141 to 144)

Page 145 Page 147 When it says "approximately one meter 1 Going to the next page, the paragraph says, 1 2 "Before induction of anesthesia, patients were 2 distance," do you know what they're referring to? 3 randomly assigned, using a computer-generated 3 A. I would assume the area where the 4 randomization sequence in which the group assignment 4 anesthesiologist is placed. 5 was kept in sequence -- sequentially numbered opaque 5 Q. Okay. One meter from there. 6 envelope, to 1 of 2 treatments: (1) Forced-Air 6 A. One meter --7 7 warming with the Bair Hugger upper body warming cover Oh, sorry. "...patients...one meter 8 (model 525) connected to a model 750 warming unit set 8 distance...environment temperature close to the... 9 to 'high' (at 43 degrees Celsius); or (2) resistive-9 approximately one meter distance." No, one me --10 polymer warming (RP group) with 2 Hot Dog warming 10 I would assume one meter distance from the 11 blankets (model: Multiposition Blanket) and the Hot 11 patient's head, which is our access, which is where we 12 Dog control unit set to 'high' (at 43 degrees 12 13 Celsius)." 13 Q. One -- one meter down or one meter up or --14 Did I read that correctly? 14 A. No. One meter in our --15 A. Yes, you do. 15 Q. Towards the anesthesiologist? MR. GORDON: Actually it's 522, not 525. 16 16 A. Good question. I don't know. 17 MR. ASSAAD: Oh, I'm sorry. 522. Thank you 17 Q. Okay. Well if you -- if you --18 counselor. 18 If going through this reminds you, please 19 Q. So it's my understanding that the control --19 let me know. Okay? 20 there are two groups, one that used the Bair Hugger 20 A. Yes. 21 750 model and the other one used the Hot Dog warming · Q. Under the "Statistical Analysis" it -- it 21 22 22 states that "A sample size of 80 patients was estimated to achieve a power of 90 percent to detect 23 A. Correct. 23 Q. Were you present for any of the testing? 24 24 equivalence within the specified equivalence bounds." 2.5 A. I can't remember, but I would assume so. 25 Did I read that correctly? Page 146 Page 148 1 Q. Okay. And it's my understanding, if you 1 A. Yes, you do. 2 look at the next column, "The core warming rate 2 Q. So a calculation was made, and to get a 3 (degree Celsius over hours) was calculated from a meaningful result you needed 80 -- 80 patients. 3 4 starting point 30 minutes after induction of 4 A. Yes. 5 anesthesia to the end of surgery..." 5 Q. Okay. And under the "RESULTS" under your 6 So you took data for that period of the 6 study it states that "There were no differences in 7 7 demographic and morphometric characteristics, except core -- core temperature. 8 A. Yes. 8 for gender with more female patients in the FA group." 9 Q. Okay. And you recorded temperatures every 9 A. Okay. 10 five minutes until the end of surgery. 10 Q. Did I read that correctly? 11 11 A. Correct. A. Yes. 12 Q. Okay. And you also took the environmental 12 Q. Okay. Having more female patients than male 13 temperature close to the patient, approximately one patients, would that make -- would that have any --13 14 meter distance and in the OR. Do you see that? It's 14 would that have any effect on core body temperature 15 about the --15 results? 16 A. Yeah, I see that. 16 A. Very little under anesthesia. 17 Q. Why was that done? 17 Q. Okay. It says, next paragraph, "After 18 A. Good question. I can't remember. 18 induction of anesthesia, core temperature decreased 19 Q. Do you remember it being done? 19 similarly for a period of approximately 30 minutes in 20 20 both groups. Subsequently, core temperature increased A. No, I don't, but it's for sure done if it's 21 here. Maybe there --21 at comparable rates in both groups (.33 degrees 22 Is there anything in the discussion that 22 Celsius per hour plus or minus .34 degrees Celsius per 23 explains it? 23 hour and .29 degrees Celsius per hour plus or minus 24 Q. Yeah, we'll get -- we'll get to it in a 24 .35 degrees Celsius per hour for groups forced-air 25 25 warming and resistive polymer, respectively..." second.

	Page 149		Page 151
1	Based on that statement, is it correct that	1	understanding is that the forced-air warming increased
2	there was no there was very little or no difference	2	the temperature around the surgical team and the
3	between the Hot Dog and the Bair Hugger units?	3 -	anesthesia team more than the conductive warming?
4	A. That's correct.	4	A. Correct.
5	Q. Okay. "There were also no differences	5	Q. Would you agree with me that it's
6	between the 2 groups in the course of core	6	Is that because the waste heat that's coming
7	temperature, mean body temperature, and mean skin	7	out of the forced-air warming is more than coming out
8	temperature" Is that a correct statement?	8	of the conductive warming?
9	A. Yes, it is.	9	A. I wouldn't call it waste heat, but yes.
10	Q. Okay. So basically what it's saying is	10	I I guess it's mainly that whatever you
11	that basically that they were almost identical.	11	get out of a convective system distributes very
12	A. Yeah. Yes.	12	differently as opposed to from a conductive system.
13	Q. Okay.	13	Q. And it causes more heat around the operating
14	A. Uh-huh.	14	room table.
15	Q. And it goes on, "We did not find significant	15	A. Yes.
16	intra intragroup core temperature differences	16	Q. Okay. That's what this study states pretty
17	between patients with esophageal and bladder core	. 17	much; correct?
18	temperature probes (results not shown)."	18	A. That's what it says, yes.
19	Is that is that the norm?	19	Q. Okay. And is that something that you were
20	A. That's what you would expect. That's	20	aware of before using forced-air warming?
21	Q. Okay. And it also goes on, the next	21	A. Yes.
22	paragraph, "No patient in this study needed	22	Q. And how were you aware of it?
23	postoperative warming in the recovery room. Thirty	23	A. Just by surgeons and nurses complaining that
24	minutes after admission to the postanesthesia recovery	24	it's warm.
25	room, the patients' thermal comfort was not different	25	Q. So so surgeons and nurses complained to
1	between forced-air warming and resistive polymer"	1	you that when they used forced-air warming, it was
2	. Did I read that correctly?	2 3	warm around the operating room table? A. Yes.
3	A. Yes. Q. And how do you measure thermal comfort using	3 4	A. Yes. Q. Approximately how many times?
4 5	a VAS?	5	A. I can't tell. It doesn't it doesn't
6	A. I assume we used a VAS. Yeah.	6	Q. Dozens, hundreds?
7	Q. What is a VAS?	7.	A. Not hundreds. I would say dozens
8	A. A visual analyst's score. So you base	8	Q. Okay.
	Q. It's objective?	9	A over 20 years.
9 10	A. It's objective. We look at	10	Q. Under the "DISCUSSION," about 15 lines down,
11	Q. Okay. Next paragraph, which I want to get	11	it says, "Some intrinsic limitations of FA" Do you
12	to, says, "The room temperature and the environmental	12	see that?
13	temperature (close proximity to the patient) were not	13	A. Yes, I see.
14	different at induction of anesthesia between	14	Q. It says, "Some intrinsic limitations of
15	forced-air warming and resistive-polymer groups. In	15	forced-air warmers include the expense of using
16	contrast, the environmental temperature in close	16	disposable blankets for each patient; the noise of the
17	proximity to the workplace of the surgical and	17	fan; and the increased OR temperature in the proximity
18	anesthesia team increased more with forced-air patient	18	of the device, resulting in thermal discomfort of the
19	warmer (at 24.4 degrees C plus or minus 5.2 degrees	19	surgical staff." Did I read that correctly?
20	Celsius for forced-air warming versus 22.6 degrees	20	A. Yes.
21	Celsius plus or minus 1.9 degrees Celsius for	21	Q. Do you agree with that statement?
22	resistive polymer at 30 minutes" with a p-value of	22	A. Yes, I do.
23	.01. Did I read that correctly?	23	Q. Okay. So so the expense of using
24	A. Yes.	24	disposable blankets is a limitation of using the Bair
		25	Hugger model.
25	Q. Okay. So is it correct that my	22	Tugger model.

38 (Pages 149 to 152)

	Page 153		Page 155
1	A. It's always more expensive, yes.	1	conductive blankets are reusable, it reduces cost.
2	Q. Than using conductive warming?	2	A. Yes, I think it does.
3	A. No, than using non-disposable devices.	3	Q. Okay.
4	Q. Okay. "Other concerns include the potential	4	A. Or it was true at that given point in time.
5	contamination of the parts of the forced-air warming	5	Q. In in 2009, 2010.
6	device (the hose and blower) with bacterial	6	A. Yeah.
7	pathogens"	7	Q. Okay. Has the price of Bair Huggers gone
8	Do you agree with that statement?	8	down, blankets, since 2010?
9	A. I guess. Otherwise, we would not have put	9	A. I believe they've gone down considerably
10	it here.	10	over the past 20 years. When exactly the changes
11	Q. Okay.	11	were, I don't know.
12	"which could be transferred by the	12	Q. Okay. So you don't know what the difference
13	airstream to the surgical field and cause infections."	13	was, the price of a Bair Hugger blanket, in 2010 as
1.4	Do you agree with that statement?	14	compared to
15	A. To a certain extent, yes.	15	A. No.
16	Q. You did not edit that statement out or have	16	Q 2016.
17	any disagreement by putting your name	.17	A. No, I do not.
18	A. When I	18	Q. Okay. Next statement, "there is possibly
19	No.	19	less warming of the OR environment, resulting in
20	Q. Okay. And I assume as an author such as	20	increased thermal comfort for OR staff" Do you
21	yourself, and a scientist, that if you specifically	21	agree with that statement?
22	disagreed with a conclusion or a statement in an	22	A. Yes, I do.
23	article, that you would not allow it to be put under	23	Q. Okay. Finally it says, "and cleaning and
24	your name.	24	disinfection are relatively easy, thus decreasing the
25	A. You're absolutely correct. That's why it	25	risk of colonization with pathogens." Do you agree
/ 	Page 154		Page 156
1	has the followup sentence here.	1	with that statement?
2	Q. I I understand that. "However, several	2	A. I did at that point in time. I actually
3	studies challenged the clinical relevance of these	3	don't any more.
4	results and found no difference in bacterial	4	Q. What caused you to change your opinion?
5	dispersion with or without forced-air warming	5	A. That it turns out that cleaning and
6	forced air;" correct?	6	disinfecting any reusable device is is more
7	A. Correct.	7	difficult and costly than we would have ever thought.
8	Q. Okay. Will you agree with me that it was an	8	Q. Okay. Based on work work staff?
9	issue with respect to the limitations of forced-air	9	A. Yeah.
10	warming that you addressed in this paper?	10	Q. Okay.
11	A. It was an issue we addressed in the	11	A. And I'm not sure whether it was or was not
12	"DISCUSSION." We did not address it in the paper	12	at that time,
13	because we didn't study it.	13	Q. Okay.
14	Q. But you address it in "DISCUSSION."	14	A but I'm not
15	A. Right.	15	Nowadays, I wouldn't completely agree with
16	Q. On the next paragraph it states, "The new	16	that.
17	warming device (Hot Dog) uses a different technology,	17	Q. So you don't know what the cost was back
18	resistive warming of a polymer blanket. Potential	18	then.
19	advantages of resistive warming compared with	19	A. No, I don't. I don't.
20	forced-air warming include the following: all parts	20	Q. Okay. It could have been the same cost it
21	of the system are reusable, thereby reducing costs and	21	is now, you're just not aware.
22	the environmental burden" Do you agree with that	22	A. Yes.
23	statement?	23	Q. Okay. Do you know what the cost of of
0.4	A. I agree.	24	cleaning a a Bair Hugger unit is?
24			
25	Q. So by the fact that the that the	25	A. No, I don't.

39 (Pages 153 to 156)

	Page 157		Page 159
1	Q. Okay. On the next column or next	1	and gentlemen of the jury understand it right. If
2	The next column, first full paragraph says,	2	you if you go to environmental temperature at one
3	"Our study demonstrates that intraoperative warming	3	meter distance to the warming device
4	with the with the resistive-polymer system was as	4	A. Which which which one is it?
5	effective as warming with the forced air system." You	5	Q after 30 minutes
6	agree with that; correct?	6	A. That's the one down here.
7 · .	A. Yes, I do.	7	Q. The Table 1.
. 8	Q. And then you continue on talking about the	. 8	A. Oh, Table 1, sorry. Environmental
9	other studies that indicated that the resistive	9	temperature. Here. Yeah, got it.
10	heating pad system was inferior to forced-air warming	10	Q. For the Bair Hugger forced-air warming, it
11	in the paragraph below that. Do you see that?	11	was 24.4 degrees plus or minus 5.2 degrees; correct?
12	A. Yes, I do.	12	A. Yes.
13	Q. Are you familiar with those studies, Russell	13	Q. So that means sometimes the temperature in
1.4	and Freeman?	14	that area was all the way up to 29.6 degrees Celsius.
15	A. Russell and Freeman I can't remember.	15	A. Yeah. Probably not quite, but
16	Q. What about Leung et al?	16	approximately, yeah.
17	A. Leung et al. You know, I can't remember.	17	Q. Okay. And then it could have gone down to
18	I'm I'm sure I knew them at some point, but I can't	18	like 19.
19	remember now.	19	A. Yeah.
20	Q. Regardless of whether I'm sorry.	20	Q. Okay. And and that would be
21	Regardless of whether or not you remember	21	Is that the standard deviation?
22	them today, would you agree with me that the	22	A. Yes, it is.
23	discussion point in this paragraph you would agree	23	Q. Okay. And for the Hot Dog, it was only 22.6
24	you agreed with at the time of the publication?	24	degrees plus or minus 1.9 degrees Celsius; correct?
25	A. I would say yes.	25	A. Uh-huh, yes.
······································			
	Page 158		Page 160
	Page 158		Page 160
1	Q. Okay. Do you agree that Russell and Freeman	1	Q. The standard deviation is much more lower
2	Q. Okay. Do you agree that Russell and Freeman had a limitation, that they used different temperature	2	Q. The standard deviation is much more lower for the Hot Dog than it is for the Bair Hugger;
2 3	Q. Okay. Do you agree that Russell and Freeman had a limitation, that they used different temperature settings for the heating pad as compared to the	2 3	Q. The standard deviation is much more lower for the Hot Dog than it is for the Bair Hugger; correct?
2 3 4	Q. Okay. Do you agree that Russell and Freeman had a limitation, that they used different temperature settings for the heating pad as compared to the forced-air warming? Do you agree with that statement?	2 3 4	Q. The standard deviation is much more lower for the Hot Dog than it is for the Bair Hugger; correct?A. Correct.
2 3 4 5	Q. Okay. Do you agree that Russell and Freeman had a limitation, that they used different temperature settings for the heating pad as compared to the forced-air warming? Do you agree with that statement? A. I don't know. I mean if it's if it's	2 3 4 5	 Q. The standard deviation is much more lower for the Hot Dog than it is for the Bair Hugger; correct? A. Correct. Q. Okay. And the p-value here, which is the
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2 3 4 5 6 7	Q. Okay. Do you agree that Russell and Freeman had a limitation, that they used different temperature settings for the heating pad as compared to the forced-air warming? Do you agree with that statement? A. I don't know. I mean if it's if it's here, I must have agreed, Q. Okay.	2 3 4 5 6 7	 Q. The standard deviation is much more lower for the Hot Dog than it is for the Bair Hugger; correct? A. Correct. Q. Okay. And the p-value here, which is the statistical significance, is .01; correct? A. Correct.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Okay. Do you agree that Russell and Freeman had a limitation, that they used different temperature settings for the heating pad as compared to the forced-air warming? Do you agree with that statement? A. I don't know. I mean if it's if it's here, I must have agreed, Q. Okay. A but I don't know today. Q. Okay. But today you have no reason to disagree with with those statements. A. No, I don't. Q. Okay. The final paragraph, it says on that paragraph, "Interestingly, the OR temperature close to the patient increased significantly at 30 minutes, corresponding to the end of surgery in the first forced-air warming group patient. Although this may have resulted in decreased OR staff members' comfort, we did not measure thermal comfort levels in this study." So you didn't measure the patient thermal comfort levels at all. A. No.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. The standard deviation is much more lower for the Hot Dog than it is for the Bair Hugger; correct? A. Correct. Q. Okay. And the p-value here, which is the statistical significance, is .01; correct? A. Correct. Q. Which means this data is statistically significant; correct? A. Different, yes. Q. Okay. Which means, based on this data, the Bair Hugger warms the air around the surgeons and the patient more than the Hot Dog; correct? A. The air is warmer, yes. Q. Okay. And that warm air is coming from underneath and around the the the warming devices; correct? MR. GORDON: Object to the form of the question. A. I assume yes. Yeah. Q. Where else would the warm air come from? A. I don't know.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Okay. Do you agree that Russell and Freeman had a limitation, that they used different temperature settings for the heating pad as compared to the forced-air warming? Do you agree with that statement? A. I don't know. I mean if it's if it's here, I must have agreed, Q. Okay. A but I don't know today. Q. Okay. But today you have no reason to disagree with with those statements. A. No, I don't. Q. Okay. The final paragraph, it says on that paragraph, "Interestingly, the OR temperature close to the patient increased significantly at 30 minutes, corresponding to the end of surgery in the first forced-air warming group patient. Although this may have resulted in decreased OR staff members' comfort, we did not measure thermal comfort levels in this study." So you didn't measure the patient thermal comfort levels at all. A. No.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. The standard deviation is much more lower for the Hot Dog than it is for the Bair Hugger; correct? A. Correct. Q. Okay. And the p-value here, which is the statistical significance, is .01; correct? A. Correct. Q. Which means this data is statistically significant; correct? A. Different, yes. Q. Okay. Which means, based on this data, the Bair Hugger warms the air around the surgeons and the patient more than the Hot Dog; correct? A. The air is warmer, yes. Q. Okay. And that warm air is coming from underneath and around the the the warming devices; correct? MR. GORDON: Object to the form of the question. A. I assume yes. Yeah. Q. Where else would the warm air come from? A. I don't know.

40 (Pages 157 to 160)

	Page 161		Page 163
1	Q. And these were orthopedic patients; correct?	1	entire belly, you have a lot open, while if you have a
2	A. Correct.	2	small incision
3	Q. Do you know what types of surgery were being	3	Q. Okay.
4	performed?	4	A there's less less heat loss from the
5	A. I thought it was hips. Did we not say that?	5	area. That's what it says there.
6	Q. It	6	Q. So the incision size has an effect on the
7	I could not find it, but if you recall	7	temperature curve of a patient with respect to his
. 8	correct if you recall	8	core temperature.
9	A. It's not good that we were not more	9	A. It might, but that's never formally been
10	specific. I I would have thought hips, but I'm	10	studied.
11	I'm not sure.	11	Q. Okay. The only thing that's really been
12	Q. And and just to	12	studied is colorectal.
13	Are you done? I'm sorry.	13	A. Right. And it was open at this point in
14	A. I'm done.	14	time.
15	Q. Okay.	15	Q. And under the "STUDY FUNDING" finally, this
16	A. I'm done.	16	was funded by Bern University Hospital?
17	Q. On the last page it says it states,	17	A. Yes.
18	"Patients undergoing very long, open surgery with	18	Q. Okay. And you you were donated
19	potential large fluid shifts are at highest risk for	19	thermocouples by Mallenckrodt Anesthesiology
20	perioperative hypothermia. In our study, the mean	20	Products?
21	duration of surgery was 90 minutes, and the typical	21	A. Yes.
22	surgery was limited to the extremities without open	22	Q. And Hot
23	abdomen and without massive fluid shifts." Did I read	23	And Augustine Biomedical Products donated
24	that correctly?	24	the the Hot Dog device; correct?
25	A. Yes.	25	A. I believe so.
	Page 162		Page 164
1	Q. Is it my understanding that patients that	1	Q. Didn't offer any funding or anything of such
2	have some sort of abdominal or open surgery in the	2.	a nature based on
3	core are much more likely to become hypothermic	3	A. No. Otherwise, it would be
· 4	because of fluid shifts as compared to patients that	4	Q. Okay. And do you know whether or not
5	undergo surgery in the extremities?	5	Augustine had any editorial say in in this
6	A. I think this is correct.	6	manuscript?
7	Q. I mean is that what this is saying pretty	7	A. I I doubt it, but I cannot remember.
. 8	much?	8	Q. Okay. Is Mercury Biomed the first company
0	A. Yes.	9	that you've been on the advisory board that's not
9		10	forced-air warming?
10	O. Okay. So for a person that has a knee		
	Q. Okay. So for a person that has a knee arthroplasty, he's less likely to become hypothermic	11	taran da antara da a
10	arthroplasty, he's less likely to become hypothermic than a person over time if you use time as a		A. I think so, yes.Q. Going back to Exhibit No. 244, do you know
10 11	arthroplasty, he's less likely to become hypothermic	11	A. I think so, yes.Q. Going back to Exhibit No. 244, do you know
10 11 12	arthroplasty, he's less likely to become hypothermic than a person over time if you use time as a constant, okay than someone that's having an	11 12	A. I think so, yes.
10 11 12 13	arthroplasty, he's less likely to become hypothermic than a person over time if you use time as a	11 12 13	A. I think so, yes.Q. Going back to Exhibit No. 244, do you know whether or not the operating rooms in Switzerland, in
10 11 12 13 14	arthroplasty, he's less likely to become hypothermic than a person over time if you use time as a constant, okay than someone that's having an abdominal surgery. A. I believe that's true.	11 12 13 14	A. I think so, yes. Q. Going back to Exhibit No. 244, do you know whether or not the operating rooms in Switzerland, in Bern in the hospital were laminar flow?
10 11 12 13 14 15	arthroplasty, he's less likely to become hypothermic than a person over time if you use time as a constant, okay than someone that's having an abdominal surgery. A. I believe that's true. Q. Okay. Is there any studies to support that,	11 12 13 14 15	 A. I think so, yes. Q. Going back to Exhibit No. 244, do you know whether or not the operating rooms in Switzerland, in Bern in the hospital were laminar flow? A. I believe the orthopedic ones were.
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10 11 12 13 14 15 16 17 18	arthroplasty, he's less likely to become hypothermic than a person over time if you use time as a constant, okay than someone that's having an abdominal surgery. A. I believe that's true. Q. Okay. Is there any studies to support that, or is that just your clinical judgment? A. That's my clinical judgment. Q. Okay. And that is because based on the fluid shifts that are occurring in an open abdominal	11 12 13 14 15 16 17 18 19	 A. I think so, yes. Q. Going back to Exhibit No. 244, do you know whether or not the operating rooms in Switzerland, in Bern in the hospital were laminar flow? A. I believe the orthopedic ones were. Q. Okay. So this study was done in a laminar flow operating room. A. I believe so. Q. And were you there during the time Do you recall being there during the
10 11 12 13 14 15 16 17 18 19 20 21	arthroplasty, he's less likely to become hypothermic than a person over time if you use time as a constant, okay than someone that's having an abdominal surgery. A. I believe that's true. Q. Okay. Is there any studies to support that, or is that just your clinical judgment? A. That's my clinical judgment. Q. Okay. And that is because based on the fluid shifts that are occurring in an open abdominal surgery as compared to an arthroplasty of a knee or	11 12 13 14 15 16 17 18 19 20	 A. I think so, yes. Q. Going back to Exhibit No. 244, do you know whether or not the operating rooms in Switzerland, in Bern in the hospital were laminar flow? A. I believe the orthopedic ones were. Q. Okay. So this study was done in a laminar flow operating room. A. I believe so. Q. And were you there during the time Do you recall being there during the surgeries?
10 11 12 13 14 15 16 17 18 19 20 21 22	arthroplasty, he's less likely to become hypothermic than a person over time if you use time as a constant, okay than someone that's having an abdominal surgery. A. I believe that's true. Q. Okay. Is there any studies to support that, or is that just your clinical judgment? A. That's my clinical judgment. Q. Okay. And that is because based on the fluid shifts that are occurring in an open abdominal surgery as compared to an arthroplasty of a knee or hip.	11 12 13 14 15 16 17 18 19 20 21 22	 A. I think so, yes. Q. Going back to Exhibit No. 244, do you know whether or not the operating rooms in Switzerland, in Bern in the hospital were laminar flow? A. I believe the orthopedic ones were. Q. Okay. So this study was done in a laminar flow operating room. A. I believe so. Q. And were you there during the time Do you recall being there during the surgeries? A. No.
10 11 12 13 14 15 16 17 18 19 20 21	arthroplasty, he's less likely to become hypothermic than a person over time if you use time as a constant, okay than someone that's having an abdominal surgery. A. I believe that's true. Q. Okay. Is there any studies to support that, or is that just your clinical judgment? A. That's my clinical judgment. Q. Okay. And that is because based on the fluid shifts that are occurring in an open abdominal surgery as compared to an arthroplasty of a knee or	11 12 13 14 15 16 17 18 19 20 21	 A. I think so, yes. Q. Going back to Exhibit No. 244, do you know whether or not the operating rooms in Switzerland, in Bern in the hospital were laminar flow? A. I believe the orthopedic ones were. Q. Okay. So this study was done in a laminar flow operating room. A. I believe so. Q. And were you there during the time Do you recall being there during the surgeries?

Page 16	5	Page 167
patients were draped during during the study?	. 1	Q. Steven Frank?
2 A. In general, yes, but I didn't supervise	2	A. Yes.
3 everything among	3	Q. How do you know Steven Frank?
4 Q. And what was your understanding of the	. 4	A. I have known him for the past 20 years.
5 draping procedure used in the the Brandt study of	- 5	Q. Is he a reputable doctor?
6 2010, Exhibit No. 244?	6	A. Absolutely.
7 A. You know what? I'm not absolutely sure. I	7	Q. And he's done research in the field,
8 could only describe to you now how you usually drape a	8	especially in in myocardial infarction?
9 hip, but whether that was absolutely done this way, I	9	A. Yes.
10 don't know.	10	Q. All right. Were you part of the meetings
Q. Do do the doctors in Switzerland drape	11	with the government or Medicare with respect to the
hips similarly to doctors in the United States?	12	SCIP protocols?
13 A. I would assume so.	13	A. No, I was not.
14 Q. Well you've practiced in Switzerland;	14	Q. Do you know why they discontinued SCIP-10?
15 A. Yes.	15	A. No, I don't.
16 Q correct?	16	Q. Do you know what SCIP-10 is?
During the time of your prac during your	17	A. I do.
practice as an anesthesiologist, did you attend or	18	Q. What is SCIP-10?
provide anesthesia services for orthopedic patients?	19	A. The
	20	As far as I understood, it was one of our
	21	performance measures in regards to temp core
Q. Okay. Going through this Exhibit 244, this	- 22	temperature of patients at the end of surgeries or at
article, does it refresh your recollection where the	23	arrival. So patients either had to have a core
temperature sensors were to measure the environmental	24	temperature at the end of surgery of greater than 36,
24 temperature?	25	or there had to be proof of active warming.
25 A. Huh-uh. The way it's		or energy and to go proof or wear o marining.
Page 16	6	Page 168
No. The way it's written, I really can't	1	Q. Okay. So if you if you active warm and
2 tell because it says once it's in the anesthesia	2	the patient is below 36 degrees,
3 surgery area, so I I really don't know.	3	A. That's fine.
4 Q. Is it possible that the one meter is just	4	Q you could file a SCIP-10.
5 one meter up from the ground?	5	A. Exactly.
6 MR. GORDON: Object to the form of the	. 6	Q. Or if it's a surgery that is short or
7 question, lack of foundation.	7	whatever, you don't and the patient comes out at 36
8 A. It's possi	8	degrees or above, you still comply with 610 or
9 MS. DIFRANCO: Go ahead.	9	SCIP-10;
10 A. Oh. No, that is not possible. I think we	10	A. Yes.
would have always done it in at patient height,	1	Q correct? Okay.
wherever the patient is.	12	(Exhibit 245 was marked for
Q. Okay. Are you familiar with the Scott study	. 1	identification.)
that looked at out of Johns Hopkins that looked at		BY MR. ASSAAD:
the SCIP-10 protocol?	15	Q. Dr. Kurz, what's been marked as Exhibit 245
16 A. Yes, I am.	16	is an article titled "Compliance with Surgical Care
17 Q. Do you know Andrew Scott?	17	Improvement Project for Body Temperature Management
18 A. Hmm?	18	(SCIP Inf-10) Is Associated with Improved Clinical
19 Q. Do you know Andrew Scott?	19	Conditions." Are you familiar with this document?
20 A. Huh-uh. Huh-uh. I don't.	20	MR. GORDON: It's "Outcomes," not
21 MS. DIFRANCO: Is that a no?	21	"Conditions."
	22	MR. ASSAAD: "Outcomes," correct.
. •		
	24	A. Yes, I am.Q. Okay. Have you looked at the data in this
	1 /.4	C. CKAY, FIAVE YOU TOOKED ALTHE DATA III IDIS
24 from Johns Hopkins?25 A. Frank.	25	document?

42 (Pages 165 to 168)

	Page 169		Page 171
1	A. Yes, I did.	1	mainly what the infections that were discovered during
2	Q. Okay. Have you had any conversations with	2	the 1996 Kurz study; correct?
3	any of the authors regarding this document?	3	A. Yes.
4	A. No, I have not.	4	Q. Okay. You agree with me that there's no
5	Q. Any conversations with Dr. Sessler regarding	5	statistically significant difference between SCIP
6	this document?	6	compliance and SCIP non-compliance.
7	A. Probably, yes.	7	A. Yes.
8	Q. Okay. If if you look at just	-8	Q. Okay. So what this is study this
9 .	Just to get a background of this of this	9	retrospective study is telling me, that in general
10	study, this was a retrospective study done at Johns	10	there's no statistical difference in wound infections
1.1.	Hopkins; correct?	11	between patients that are SCIP compliant, which is
12	A. Correct.	12	either active warming or or they maintain
13	Q. And it was regarding	13	normothermia, and SCIP non-compliant; is that correct?
14	And they looked at 46,683 patients that	14	A. I assume it is.
15	underwent non-cardiac surgery between January 2010 and	15	Q. Okay. And you have no reason to disagree
16	June 2014; is that correct?	16	with these numbers; correct?
17	A. That is	17	A. Other than that they're very small, no.
1.8	If I find it here, it's correct.	18	Q. For for wound infection, I mean this
19	Q. On the second page.	1.9	forty forty-three thousand patients.
20	A. Oh, you're back there. Okay.	20	A. Right. But 44 SCIP non-compliant wound
21	Q. Under "Materials and Methods."	21	infections.
22	A. Okay. Yeah.	22	Q. Yeah, 44 out of 44,000.
23	Q. Okay. And on the following column where it	23	A. Forty-four out of 1,200.
24	starts with "Two groups," it says, "Two groups were	24	Q. Where do you get 1,200?
25	created based on the SCIP-10 guideline, which was	25	A. In the same
	Page 170		Page 172
	·		
1	designed to be the 'SCIP compliant' and 'SCIP	1	
1 2	designed to be the 'SCIP compliant' and 'SCIP noncompliant' groups. If the highest of the two	1 2	Q. Oh, okay.
2	noncompliant' groups. If the highest of the two	2	Q. Oh, okay. A. So it's
2 3	noncompliant' groups. If the highest of the two temperatures measured during the last 30 minutes of		Q. Oh, okay. A. So it's Anyway,
2 3 4	noncompliant' groups. If the highest of the two temperatures measured during the last 30 minutes of surgery and the first 15 minutes of postoperative care	2 3 4	Q. Oh, okay. A. So it's Anyway, Q. Okay.
2 3 4 5	noncompliant' groups. If the highest of the two temperatures measured during the last 30 minutes of surgery and the first 15 minutes of postoperative care was greater than or equal to 36 degrees, or active	2 3 4 5	 Q. Oh, okay. A. So it's
2 3 4	noncompliant' groups. If the highest of the two temperatures measured during the last 30 minutes of surgery and the first 15 minutes of postoperative care	2 3 4	 Q. Oh, okay. A. So it's
2 3 4 5 6	noncompliant' groups. If the highest of the two temperatures measured during the last 30 minutes of surgery and the first 15 minutes of postoperative care was greater than or equal to 36 degrees, or active patient warming was utilized" A. Correct.	2 3 4 5 6	 Q. Oh, okay. A. So it's
2 3 4 5 6 7 8	noncompliant' groups. If the highest of the two temperatures measured during the last 30 minutes of surgery and the first 15 minutes of postoperative care was greater than or equal to 36 degrees, or active patient warming was utilized" A. Correct. Q. And that's what we discussed previously;	2 3 4 5 6 7 8	 Q. Oh, okay. A. So it's
2 3 4 5 6 7 8	noncompliant' groups. If the highest of the two temperatures measured during the last 30 minutes of surgery and the first 15 minutes of postoperative care was greater than or equal to 36 degrees, or active patient warming was utilized" A. Correct. Q. And that's what we discussed previously; correct?	2 3 4 5 6 7 8	 Q. Oh, okay. A. So it's
2 3 4 5 6 7 8 9	noncompliant' groups. If the highest of the two temperatures measured during the last 30 minutes of surgery and the first 15 minutes of postoperative care was greater than or equal to 36 degrees, or active patient warming was utilized" A. Correct. Q. And that's what we discussed previously; correct? A. Yes.	2 3 4 5 6 7 8 9	 Q. Oh, okay. A. So it's
2 3 4 5 6 7 8	noncompliant' groups. If the highest of the two temperatures measured during the last 30 minutes of surgery and the first 15 minutes of postoperative care was greater than or equal to 36 degrees, or active patient warming was utilized" A. Correct. Q. And that's what we discussed previously; correct? A. Yes. Q. Okay. Now if you look on Table 2, they	2 3 4 5 6 7 8	 Q. Oh, okay. A. So it's
2 3 4 5 6 7 8 9 10	noncompliant' groups. If the highest of the two temperatures measured during the last 30 minutes of surgery and the first 15 minutes of postoperative care was greater than or equal to 36 degrees, or active patient warming was utilized" A. Correct. Q. And that's what we discussed previously; correct? A. Yes. Q. Okay. Now if you look on Table 2, they looked and not just colorectal surgery but over many	2 3 4 5 6 7 8 9 10	Q. Oh, okay. A. So it's Anyway, Q. Okay. A I believe the data, but it it has problems. Q. Do you think it's underpowered? A. I don't want to talk about power here. I would have to really reread that article because I know I had some concerns about it. I just can't remember them now. Q. Okay. Now this is not saying that, if you
2 3 4 5 6 7 8 9 10 11	noncompliant' groups. If the highest of the two temperatures measured during the last 30 minutes of surgery and the first 15 minutes of postoperative care was greater than or equal to 36 degrees, or active patient warming was utilized" A. Correct. Q. And that's what we discussed previously; correct? A. Yes. Q. Okay. Now if you look on Table 2, they looked and not just colorectal surgery but over many different types of surgeries; correct?	2 3 4 5 6 7 8 9 10 11	Q. Oh, okay. A. So it's Anyway, Q. Okay. A I believe the data, but it it has problems. Q. Do you think it's underpowered? A. I don't want to talk about power here. I would have to really reread that article because I know I had some concerns about it. I just can't remember them now. Q. Okay. Now this is not saying that, if you look at the individual type of surgeries, that you're
2 3 4 5 6 7 8 9 10 11 12 13	noncompliant' groups. If the highest of the two temperatures measured during the last 30 minutes of surgery and the first 15 minutes of postoperative care was greater than or equal to 36 degrees, or active patient warming was utilized" A. Correct. Q. And that's what we discussed previously; correct? A. Yes. Q. Okay. Now if you look on Table 2, they looked and not just colorectal surgery but over many different types of surgeries; correct? A. Correct.	2 3 4 5 6 7 8 9 10 11 12 13	Q. Oh, okay. A. So it's Anyway, Q. Okay. A I believe the data, but it it has problems. Q. Do you think it's underpowered? A. I don't want to talk about power here. I would have to really reread that article because I know I had some concerns about it. I just can't remember them now. Q. Okay. Now this is not saying that, if you look at the individual type of surgeries, that you're not going to see a statistically significant
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	noncompliant' groups. If the highest of the two temperatures measured during the last 30 minutes of surgery and the first 15 minutes of postoperative care was greater than or equal to 36 degrees, or active patient warming was utilized" A. Correct. Q. And that's what we discussed previously; correct? A. Yes. Q. Okay. Now if you look on Table 2, they looked and not just colorectal surgery but over many different types of surgeries; correct? A. Correct. Q. General surgery, gynecology, neurosurgery, spine, orthopedics, otolaryngology, plastics, pediatric surgery, thoracic, transplant, urology, and vascular; correct? A. Uh-huh. Correct.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. Oh, okay. A. So it's Anyway, Q. Okay. A I believe the data, but it it has problems. Q. Do you think it's underpowered? A. I don't want to talk about power here. I would have to really reread that article because I know I had some concerns about it. I just can't remember them now. Q. Okay. Now this is not saying that, if you look at the individual type of surgeries, that you're not going to see a statistically significant difference; correct? A. Correct. Q. You're looking at the overall trend. A. Correct. Q. Okay. And and if you turn to Table 3,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	noncompliant' groups. If the highest of the two temperatures measured during the last 30 minutes of surgery and the first 15 minutes of postoperative care was greater than or equal to 36 degrees, or active patient warming was utilized" A. Correct. Q. And that's what we discussed previously; correct? A. Yes. Q. Okay. Now if you look on Table 2, they looked and not just colorectal surgery but over many different types of surgeries; correct? A. Correct. Q. General surgery, gynecology, neurosurgery, spine, orthopedics, otolaryngology, plastics, pediatric surgery, thoracic, transplant, urology, and vascular; correct? A. Uh-huh. Correct. Q. Okay. So they looked at the effect of SCIP	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Q. Oh, okay. A. So it's Anyway, Q. Okay. A I believe the data, but it it has problems. Q. Do you think it's underpowered? A. I don't want to talk about power here. I would have to really reread that article because I know I had some concerns about it. I just can't remember them now. Q. Okay. Now this is not saying that, if you look at the individual type of surgeries, that you're not going to see a statistically significant difference; correct? A. Correct. Q. You're looking at the overall trend. A. Correct. Q. Okay. And and if you turn to Table 3, what's what's interesting is the paper
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	noncompliant' groups. If the highest of the two temperatures measured during the last 30 minutes of surgery and the first 15 minutes of postoperative care was greater than or equal to 36 degrees, or active patient warming was utilized" A. Correct. Q. And that's what we discussed previously; correct? A. Yes. Q. Okay. Now if you look on Table 2, they looked and not just colorectal surgery but over many different types of surgeries; correct? A. Correct. Q. General surgery, gynecology, neurosurgery, spine, orthopedics, otolaryngology, plastics, pediatric surgery, thoracic, transplant, urology, and vascular; correct? A. Uh-huh. Correct. Q. Okay. So they looked at the effect of SCIP compliance or maintaining normothermia over many	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. Oh, okay. A. So it's Anyway, Q. Okay. A I believe the data, but it it has problems. Q. Do you think it's underpowered? A. I don't want to talk about power here. I would have to really reread that article because I know I had some concerns about it. I just can't remember them now. Q. Okay. Now this is not saying that, if you look at the individual type of surgeries, that you're not going to see a statistically significant difference; correct? A. Correct. Q. You're looking at the overall trend. A. Correct. Q. Okay. And and if you turn to Table 3, what's what's interesting is the paper A. I don't
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	noncompliant' groups. If the highest of the two temperatures measured during the last 30 minutes of surgery and the first 15 minutes of postoperative care was greater than or equal to 36 degrees, or active patient warming was utilized" A. Correct. Q. And that's what we discussed previously; correct? A. Yes. Q. Okay. Now if you look on Table 2, they looked and not just colorectal surgery but over many different types of surgeries; correct? A. Correct. Q. General surgery, gynecology, neurosurgery, spine, orthopedics, otolaryngology, plastics, pediatric surgery, thoracic, transplant, urology, and vascular; correct? A. Uh-huh. Correct. Q. Okay. So they looked at the effect of SCIP compliance or maintaining normothermia over many different types of surgeries.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Oh, okay. A. So it's Anyway, Q. Okay. A I believe the data, but it it has problems. Q. Do you think it's underpowered? A. I don't want to talk about power here. I would have to really reread that article because I know I had some concerns about it. I just can't remember them now. Q. Okay. Now this is not saying that, if you look at the individual type of surgeries, that you're not going to see a statistically significant difference; correct? A. Correct. Q. You're looking at the overall trend. A. Correct. Q. Okay. And and if you turn to Table 3, what's what's interesting is the paper A. I don't Q. Table 3.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	noncompliant' groups. If the highest of the two temperatures measured during the last 30 minutes of surgery and the first 15 minutes of postoperative care was greater than or equal to 36 degrees, or active patient warming was utilized" A. Correct. Q. And that's what we discussed previously; correct? A. Yes. Q. Okay. Now if you look on Table 2, they looked and not just colorectal surgery but over many different types of surgeries; correct? A. Correct. Q. General surgery, gynecology, neurosurgery, spine, orthopedics, otolaryngology, plastics, pediatric surgery, thoracic, transplant, urology, and vascular; correct? A. Uh-huh. Correct. Q. Okay. So they looked at the effect of SCIP compliance or maintaining normothermia over many	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Oh, okay. A. So it's Anyway, Q. Okay. A I believe the data, but it it has problems. Q. Do you think it's underpowered? A. I don't want to talk about power here. I would have to really reread that article because I know I had some concerns about it. I just can't remember them now. Q. Okay. Now this is not saying that, if you look at the individual type of surgeries, that you're not going to see a statistically significant difference; correct? A. Correct. Q. You're looking at the overall trend. A. Correct. Q. Okay. And and if you turn to Table 3, what's what's interesting is the paper A. I don't

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Page 173 Page 175 1 of infections. So I would need to reread that. 1 A. I assume, yeah. 2 Q. DK is probably a typo because there's no DK 2 Okay, Table 3. listed here, and CL is Claude LaFlamme. Do you know 3 3 Q. Okay. I'm talking about --Claude LaFlamme? 4 But wound infections, you agree with me that 4 5 5 there's no statistically significant difference based A. I do. 6 on this data. 6 Q. Okay. And this is based from a question, if A. Yes. you go up, "why should 3M fund a study to show risk 7 7 Q. Okay. Table 3 talks about SCIP compliant 8 associated with hypothermia when there's already broad 8 9 and SCIP non-compliant, and for SCIP non-compliant 9 acceptance of the current evidence?" And one of your 10 means that you're not above 36 degrees and you 10 responses is, "...since you've already proven out the risks of 2 degrees of hypo. Worse case it would show 11 received no active warming; correct? 11 1 degree doesn't matter." Did I read that correctly? 12 12 A. And/or, yes. 13 13 Q. Okay. So there's no active warming, and you Q. Okay. So sitting here today, you don't know do not leave the operating room at 36 degrees, 14 14 if one degree of hypothermia has any effect on according to the criteria, or within 15 minutes --15 15 infection rates. 16 16 A. Right. A. Yes. Q. Okay. And -- and for those patients, we're 17 17 Q. Correct? 18 seeing an end operating room temperature -- core 18 19 temperature of 35.1 degrees. 19 A. I think I've said that several times. 20 A. Yeah. 2.0 Q. Okay. So if --21 Q. Okay. So that that's higher than, you know, 21 And that's one degree below 36 degrees; the uncooled patients in your study that were 34.5 22 correct? 22 23 23 A. I can't remember how we -- one -- one degrees. degree. It's --24 24 A. That's right. O. And we're seeing patients -- the difference 25 No, I would say it's one degree below core 2.5 Page 174 Page 176 between the SCIP compliant and the non-SCIP 1 temperature. 1 2 Q. Well what we --2 compliant -- let's start with this -- withdraw. The difference with the SCIP compliant and 3 3 I mean do you remember what you were talking 4 about here? Were you talking about core temperature 4 the SCIP non-compliant, we're looking about -- a 5 5 change of temperature of about, what, 1.2 degrees on 6 A. I can't remember. 6 average. 7 7 Q. Okay. Q. Okay. You agree with me sitting here today 8 A. I cannot, no. 8 9 that there's no evidence that a one-degree change of 9 Q. Well if these studies are showing that the 10 core temperature is less than one -- one degree 10 temperature in the core body temperature has any 11 with -- with non-compliant patients at 35.1 --11 effect on infection rates. 12 A. Uh-huh? 12 A. I agree that there's very little evidence 13 13 Q. Okay. for that, yes. -- and there's no evidence to support active 14 Q. And if you look at page six of Exhibit No. 14 warming at that point, what evidence is there to 15 15 218 --support active warming and maintaining normothermia in 16 16 A. Which is what? 17 2016? 17 Give me one second with this one here, A. I think there is a little ev -- evidence 18 please. How did they measure that? 18 19 Which one? 19 that we have from 20 years ago. Q. Little evidence -- excuse me? 20 20 Q. Exhibit 218, --21 A. Oh. 21 A. That the --Q. -- page six. Under the seventh line up it 22 22 It's in fact still there, old woundsays AK, DK, CL. Do you see that? 23 infection study we did, which might not be to today's 23 24 standards but very much was to standards at that point 24 A. Seventh line up. Yeah. 25 in time. This study doesn't prove that the opposite 25 Q. Okay. And AK is you; correct?

			Page 179
1	is true either, because don't forget, it's a	1	A. Very little.
. 2	retrospective study and not one of the best-done	. 2	Q. None; correct?
3	either. So you	3	A. I'm not quite sure. I'm I'm still I'm
4	Q. Based on in today's standards.	4	still debating about blood loss and other studies.
5	A. Based on in today's standards.	5	Q. Talking about infection.
. 6	Q. Okay. It might have been good standards	6	A. Yeah.
7	back in 1996.	7	Q. So I just want to get this clear for the
8	A. There's no discussion about it because the	8	record. You agree with me that, in today's scientific
9	data would not have been available in '96.	9	community, that there's no evidence, publishable
10	Q. Okay.	10	evidence that supports that maintaining normothermia
.11	A. So we still only have the old data.	11	reduces infection rates. You agree with that
12	Q. Okay. And Dr. Sessler has mentioned in an	12	statement.
13	e-mail before, in today's standards and with respect	13	A. Still have problems with that statement.
14	to reliability of studies, that he probably wouldn't	1.4	Q. Do you want me to rephrase?
15	have published the 1996 Kurz paper. Do you agree with	15	A. Yeah. Do that, please.
16	him?	16	Q. In today's scientific standards, there is no
17	A. Absolutely.	17	reliable evidence that supports that maintaining
18	Q. Okay.	18	normothermia reduces the incidence of infection.
19	A. I would not have either.	19	A. That is correct.
20	Q. So without that paper meeting today's	20	Q. Thank you.
21	standards, do you agree with me that there's no	21	MR. ASSAAD: Take a break. I need to use
22	scientific evidence today that active warming or	22	the restroom.
23	maintaining normothermia reduces the incidence of	23	THE REPORTER: Off the record, please.
24	infection?	24	(Recess taken.)
25	A. If I mean if if you exclude the only	25	BY MR. ASSAAD:
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-	Page 178		Page 180
1	paper that shows that, then there is no evidence.	1	Q. Going going back to my last question: In
2	Q. Well we discussed later there's only one	2	fact, as early as 2012 you notified 3M that the
3	paper regarding infection rates; correct?	3	current research guidelines for reliability and that
4	A. You could	4	the previous studies were not done were done with
5 .	You have a second one which you excluded:	5	much I'm sorry. Rephrase.
6	the Melling paper.	6	Back in 2012 you notified 3M that, at the
7	Q. Well you couldn't tell me whether or not	7	KOL meeting in Washington, that the evidence for
. 8	that was intraoperative warming; correct?	8	hypothermia-related complications mostly does not meet
9	MR. GORDON: Objection.	9	current research guidelines for reliability and that
10	A. It doesn't matter.	10	previous studies were done with much larger
. 11	Q. Okay.	11	temperature differences than are currently allowed.
12	A. It does not matter. We are talking about	12	Do you recall saying that to 3M?
13	maintenance of normothermia,	13	A. That is correct.
14	Q. Okay.	14	Q. Okay. And are you aware since that time 3M
15	A whether you warm the patients	15	has continued to cite your paper for its marketing
16	Q. Do you think Melling was a good study?	16	purposes with respect to its claim that forced-air
17	A. It was an okay study for the time.	17	warming is a way to maintain normothermia, which
18	Q. Would you agree with me that that wouldn't	18	reduces the incidence of infection?
19	be publishable today?	19	A. I agree with this.
20	A. I absolutely would agree with you.	20	Q. You agree that you're aware that mar that
21	Q. Okay. So sitting here today, what paper	21	they continue their marketing.
22	that could that what evidence that could be	22	A. Yes. And I agree that they do that. I do
	published today supports active warming in the in	23	the same.
23			
24	the active warming and normothermia that reduces the	24	Q. Okay. And you've been requesting from them
		24 25	Q. Okay. And you've been requesting from them since 2012, you and Dr. Sessler, to fund studies to

	Page 181		Page 183
1	larger studies to support those claims that were made	1	me some examples?
2	or those observations or or results that were found	2	A. Yeah. Your eye.
3	in the Kurz study; correct?	3	Q. Okay. What about surgeries lasting less
4	A. That's partially correct. We asked to do a	4	than an hour?
5	study, first of all, larger patient populations but	5	A. I
6	more importantly smaller temperature differences. And	6	With current knowledge, I probably would
7	the smaller temperature differences we only have	7	agree that active warming might not be needed.
8	nowadays because all patients are warmed; otherwise,	8	(Exhibit 246 was marked for
9	we would still think my '96 paper is very relevant.	9	identification.)
10	Q. But you're still looking at just colorectal;	10	BY MR. ASSAAD:
11	correct?	11	Q. Dr. Kurz, what has been marked as Exhibit
12	A. No, we are not.	12	246 is an e-mail from Al Van Duren to you and Dr.
13	Q. Well on the on the Protect study it's	13	Sessler, at the bottom part of the e-mail, regarding
14	colorectal.	14	two drafts of temperature papers that were coming up
15	A. Protect study says any type of	15	for publication in 2013. Do you recall receiving this
16	Q. Okay.	16	e-mail?
17	A other than any type of non-cardiac	17	A. I don't.
18	surgical patient population.	18	Q. Do you know what two papers he's referring
19	Q. And when is that study supposed to be	19	to?
20	completed?	20.	A. I don't. I assume one is the descriptive
21	A. I would	21	temperature study, the
22	Well, you should never ask things like that.	22	Q. Targeting Normothermia?
23	It's three years.	23	A. No, not Targeting Normothermia. The one we
24	Q. Three years from	24	discussed before that included transfusions.
25	A. Three years from now.	25	Q. Okay.
- 		ļ	
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1	Page 182	1 1	Page 184
1	Q. Okay.	1 2	A. I assume that
2	Q. Okay. A. From the beginning, yeah. But it should be	2	A. I assume that Q. They they funded that study; correct?
2 3	Q. Okay.A. From the beginning, yeah. But it should be beginning soon, should be beginning soon.	2 3	A. I assume thatQ. They they funded that study; correct?A. I think they did.
2 3 4	 Q. Okay. A. From the beginning, yeah. But it should be beginning soon, should be beginning soon. Q. Do you agree that not all patients need to 	2 3 4	 A. I assume that Q. They they funded that study; correct? A. I think they did. Q. Yeah. Okay. And what was the other one?
2 3 4 5	 Q. Okay. A. From the beginning, yeah. But it should be beginning soon, should be beginning soon. Q. Do you agree that not all patients need to be actively warmed? 	2 3 4 5	 A. I assume that Q. They they funded that study; correct? A. I think they did. Q. Yeah. Okay. And what was the other one? A. I don't know because there's no other one
2 3 4 5 6	 Q. Okay. A. From the beginning, yeah. But it should be beginning soon, should be beginning soon. Q. Do you agree that not all patients need to be actively warmed? A. Yes, I do agree. 	2 3 4 5 6	 A. I assume that Q. They they funded that study; correct? A. I think they did. Q. Yeah. Okay. And what was the other one? A. I don't know because there's no other one be we we we've published.
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	Page 185		Page 187
. 1	would put that disclaimer in an e-mail to you?	1	that that it won't it won't hold under scrutiny
2	A. I cannot even remember which two papers	2	in the future?
3	those were.	-3	A. I might have. I don't know.
4	Q. Dr. Sessler responded	4	Q. Do you recall any conversations with
5	A. I don't know.	5	Michelle Hulse Stevens about informing her that the
6	Q to Al Van Duren, "Dear Al,	6	1996 study is not reliable and we need or it's
7	"We are in the process of submitting the	. 7	not doesn't meet today's reliability standards and
8	papers. Thus, every comment would have to be	8	that we should get funding for a new study?
9	incorporated really quickly. I assume, if we get your	9	A. Might very well be.
10	suggestions by next week we can still incorporate	10	Q. Do you recall having a pitch or proposal
11	them." Did I read it correctly?	11	to to Michelle Hulse Stevens?
12	A. Yes, you did.	12	A. I'm sure we had over the last few years.
13	MR. GORDON: Read the signature. I think	13	Q. But you don't recall anything
14	you misspoke.	14	A. I don't recall when or why and
15	Q. Oh, I'm sorry. It was from you. Sorry.	15	Q. You you agree that there's part of the
16	This is an e-mail from you to Al Van Duren; correct?	16	scientific community that believes that there's not
17	A. Yeah. I don't know which the second paper	17	enough scientific evidence to support maintaining
18	was. I'm sorry.	18	normothermia during the intraoperative period.
19	Q. Well whatever paper it was, you were willing	19	MR. GORDON: Object to the form of the
. 20	to hear suggestions from Al Van Duren and incorporate	20	question.
21	them into a paper.	21	A. I actually don't believe that.
22	A. Obviously, yes. Yeah.	22	Q. You've never read any articles by doctors in
23	Q. Okay. Do you know whether both papers were	23	South Carolina that talk about normothermia being
24	funded by 3M?	24	being as a false idol?
25	A. If I don't know which the second one was, I	25	A. No. Who who was that?
		-	
1			
	Page 186	.:	Page 188
1	Page 186	1	Page 188 MS. DIFRANCO: Answer his questions.
1 2	•	1 2	
	don't know, no.	I	MS. DIFRANCO: Answer his questions. THE WITNESS: Yeah. No. MS. DIFRANCO: You can't ask him questions.
2	don't know, no. Q. Well I guess my question	2	MS. DIFRANCO: Answer his questions. THE WITNESS: Yeah. No.
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	Page 189		Page 191
1	Q. So you think you may have told 3M that you	1	associated with a reduced incidence of hospital-
2	can't make those claims?	2	acquired infections," then they go on to give the
3	A. I may have had a conversation, but I	3	numbers and the odds ratio.
4	really in 20 years, I I don't remember that.	4	Would you consider the Scott paper evidence
5	Q. Would it have been with Dr. Augustine?	5	that maintenance of normothermia has a beneficial
6	A. I had very few conversations with Dr.	6	impact by in in in terms of reducing the
7	Augustine.	7	incidence of hospital-acquired infection?
8	Q. Has Dr. Augustine ever asked you to be on	. 8	MR. ASSAAD: Objection to form.
9	his advisory board for Hot Dog?	9	A. I do. I I do. And that's what I
10	A. He might have many years ago.	10	actually wanted to get to. I mean only that this is a
11	MR. ASSAAD: I think that's all I have.	11	retrospective study. Wound infections are very, very
12	MR. GORDON: Yeah. And given the doctor's	12	poorly coded; however, they did have things like
13	need to finish in a half	13	sepsis and other really, really important infectious
14	THE WITNESS: No, it's fine.	14	outcomes that were reduced. So in the end, I don't
15	MS. DIFRANCO: Let's keep going for	15	care which type of infection it is,
16	Let's go off the record.	16	Q. And
17	THE REPORTER: Off the record, please.	17	A that it's clear there is a positive
18	(Discussion off the stenographic record.)	18	effect or a decreased infection incidence in patients
19	BY MR. GORDON:	19	that were SCIP compliant.
20	Q. Dr. Kurz, I'm Corey Gordon. I represent 3M.	20	Q. And by "SCIP compliant," that that means
21	I want to start with asking you some	21	maintenance of normothermia.
22	follow-up questions on Exhibit 245. That's the Scott	22	A. Either
23	paper.	23	MR, ASSAAD: Objection.
24	A. Uh-huh.	24	A greater than 36 and/or warmed
25	Q. SCIP Inf-10.	25	intraoperatively.
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	Page 190		
	Page 190		Page 192
. 1	A. SCIP-10. Yeah. Where did I put that?	1	Q. Okay. And on page five they under
. 2	A. SCIP-10. Yeah. Where did I put that?Q. It's right there. I I'm	2	Q. Okay. And on page five they under "Discussion" they go they say that "The primary
2 -3	A. SCIP-10. Yeah. Where did I put that?Q. It's right there. I I'm I want to clarify because I'm not sure I	2 3	Q. Okay. And on page five they under "Discussion" they go they say that "The primary findings in this study were that SCIP Inf-10
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2 3 4 5	A. SCIP-10. Yeah. Where did I put that? Q. It's right there. I I'm I want to clarify because I'm not sure I heard you correctly. Are you Is it your testimony that there is no	2 3 4 5	Q. Okay. And on page five they under "Discussion" they go they say that "The primary findings in this study were that SCIP Inf-10 compliance was associated with a reduced risk for hospital hospital-acquired infections, ischemic
2 3 4 5 6	A. SCIP-10. Yeah. Where did I put that? Q. It's right there. I I'm I want to clarify because I'm not sure I heard you correctly. Are you Is it your testimony that there is no evidence today to support the notion that maintenance	2 3 4 5 6	Q. Okay. And on page five they under "Discussion" they go they say that "The primary findings in this study were that SCIP Inf-10 compliance was associated with a reduced risk for hospital hospital-acquired infections, ischemic cardiovascular events, and mortality, as well as a
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	Page 193		Page 195
1	ago, it's under different conditions, but that's the	1	presence of any benefit from the maintenance of
2	body of literature we have at the moment.	· 2	normotherm normothermia on wound infections,
3	Q. And in a little bit further on they go on to	3	specifically in the context of orthopedic procedures,
4	say, "Our findings also support those of the original	4	do you do you believe this study has any has any
5	randomized clinical trials by Kurz et al and Frank et	5	value?
6	al, on which the SCIP measure was based"	6	MR. ASSAAD: Objection to form, assumes
7	A. Right.	7	facts not in evidence.
8	Q. So by	8	Q. That's that's a that's a poor
9	Okay. Right. And I so are are	9	question,
10	Do you consider the Scott study or the Scott	10	A. Yeah.
11	paper to somehow call into question your original	11	Q poorly-phrased question.
12	paper, the 1996 paper?	12	MR. ASSAAD: I interrupted. I'm sorry.
13	MR. ASSAAD: Objection to form.	13	Q. Would would would you consider this
14	A. I don't, despite the fact that the the	14	study evidence that maintenance of normothermia
15	strict wound infections don't seem to be different,	15	confers no benefit in orthopedic surgery
16	but I'm not taking it so seriously because those are	16	MR. ASSAAD: Objection
17	usually very hard to evaluate. So I absolutely agree	17	Q in terms of reducing the risk of
18	with that paper.	18	infection?
19	Q. And on with respect to that, I think	19	MR. ASSAAD: Objection to form, assumes
20	they they I I'd like to direct your	20	facts not in evidence.
21	attention to page six	21	A. Let let me rephrase that.
22	A. Just one further, yeah.	22	Q. Please.
23	Q. On the the bottom of the first full	23	A. I con
24	paragraph they say, "We also had a lower risk	24	I think in regards to orthopedic surgery and
25	population for wound infection compared with the	2,5	wound infections, these patients, this study cannot
		<u></u>	
	Page 194		Page 196
1	_	1	
1 2	Page 194 randomized trial by Kurz et al, where all patients had colorectal surgery. This may explain why in our study	1 2	Page 196 make a statement not make any statements. Q. Okay. And have have you are
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	Page 197		Page 199
1	data just because they had such low numbers of those,	1	population;
2	which is very, very typical for retrospective studies.	2	A. Yes.
3	It's like not in our colorectal patients we exactly	3	Q is that right?
4	evaluate that every day. These are just electronic	4	A. Yeah.
5	data where it's not done.	5 -	I couldn't redo the study, the exact study,
6	The other objection not objection, but	6	no.
7	the other thing I I didn't agree so much was their	7	Q. Please explain to the jury why you couldn't
8	temperature data, whether SCIP compliant or	8	redo the study today.
9	non-compliant, because it's not completely clear how	9	A. Because it would be considered unethical
10	they measured that, whether it was esophageal I	10	nowadays not to warm a patient at all
11	think most of it was actually some type of infrared or	11	intraoperatively. No eth
12	so measurement which isn't very reliable.	12	Q. Fine.
13	So those were my main concerns, which in the	13	A. No ethics committee it's become
14	end don't make don't matter that much because	14	Over the past 20 years, active warming has
15	temperature is is is a side effect here.	15	become standard of care, and with no study you can
16	They they looked at SCIP compliant or non. So	16	deviate from the standard of care. So 20 years ago,
17	yeah, so they should have fairly accurate temperature	17	having a control group that wasn't actively warmed was
18	measurements.	18	perfectly fine because nobody else in the world warmed
19	Q. Okay. So your your 1996 study,	19	patients. Nowadays it wouldn't.
20	A. Yes.	20	The other thing is, of course and that's
21	Q your you said it wouldn't you	21	one reason why we are looking at much larger patient
22	wouldn't consider it publishable today. What are the	22	populations. Due to the fact the patients are warmed,
23	reasons for that?	23	we don't see the significant decrease of hypothermia
24	A. I'm I	24	any more, and therefore in any study the effect size
25	Did I really say that I wouldn't consider it	25	wouldn't be as large as in this particular one.
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1 2	publishable?	1 2	Q. I under
2	publishable? Q. II	2	Q. I under Putting aside the ethical your your
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2 3 4 5	 publishable? Q. I I A. I don't think I said it in those words. Q. I Don't let me to put well don't let me put 	2 3 4	Q. I under Putting aside the ethical your your constraint that would prevent you from doing a study without an act without active warming, A. Uh-huh.
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50 (Pages 197 to 200)

Page 201 Page 203 1 saying -- or are you saying that you -- you -- that 1 Cleveland Clinic and many other places nowadays. 2 the evidence today no longer supports the idea that 2 Q. So in terms of that, you know, evidence 3 act -- that maintenance of normothermia reduces the 3 supporting the notion that normothermia confers a 4 risk of surgical-site infections? 4 benefit in terms of reducing the risk of infection, MR. ASSAAD: Objection to form. 5 5 perhaps the evidence for the reduced transfusions is 6 A. I think, if I understand you correctly, I'm not direct A-to -- A-to-B evidence but it's 6 7 not saying that. I am saying that I still believe 7 A-to-B-to-C. 8 that maintenance of normothermia decreases infection 8 A. It's a mediator. 9 risk, but the effect size might be closer to 30-9 MR. ASSAAD: Objection to form. 10 percent reduction or so, which in effect is a 10 Q. I'm sorry. You -- you said it was --11 humongous, enormously large effect size for any 11 A. It's almost like a mediator. So if you 12 medical intervention. 12 are -- it -- or it's -- it's a --13 Q. And you were asked about some -- apparently 13 It's part of a mechanism, let's put it that 14 some doctors in South Carolina who -- who seem to 14 way. So if you are hypothermic, you lose more blood. 15 think that maintenance of normothermia is -- is 15 And that's actually pretty well established, because 16 completely unimportant. Would you -- is that 16 hypothermia directly affects platelet function. If 17 17 something with which you -you -- if you -- if you give transfusions, then you 18 Are you familiar with any sizeable or, you 18 get some immunosuppressive effect and -- which 19 know, appreciable number of physicians or school of 19 decreases the host response which then could -- but 20 thought that actually is -- questions the -- the value 20 I'm extrapolating now, so --21 of normothermia today? 21 But that's the clinical pathway which I 22 A. No, I'm not. That's why I was so surprised. 22 think that follows. 23 No, I'm not. 23 Q. And the study that you're -- you and Dr. 24 Q. In fact, have you ever heard of any doctors 24 Sessler are doing now in China, what -- what's the 25 who question normothermia as -- as a -- as a positive 25 primary outcome that you're -- you're looking at Page 202 Page 204 1 benefit? 1 there? 2 2 A. Not in the past 10 years or 15 years. A. I think the primary outcome is myocardial 3 3 Q. Okay. You had -- and -injury after non-cardiac surgery, but I do believe --4 And you earlier talked about more-recent 4 we've gone over the protocol so often that I'm getting 5 studies that you -- that meet the more-modern 5 confused - that the secondary outcome is wound 6 6 standards of evidence -- evidence-based medi -infection. 7 7 medicine to support the positive impact of Q. But in terms of primary infection, the 8 8 myocardial injury, is that -- is -- is -- is the -normothermia on several other outcomes. 9 9 the injury that you're looking -- you're going to be 10 Q. Okay. We talked -- you --10 looking for, is that something that -- that the -- the 11 11 average patient would realize they've been injured? You talked about blood transfusions. And if 12 it reduces the need for blood transfusion. 12 MR. ASSAAD: Object to the form, 13 13 does -- does that have any potential to impact the --A. Yes, it is, because they either would have a 14 the host immunity? 14 myocardial infarction after surgery, which they would 15 A. Enormously, yes. 15 know very well, or they would have some type of injury 16 16 Q. Yeah. How so? which is not quite as bad but still a bad complication 17 A. Because blood transfusions in itself are to 17 after surgery. And myocardial injury after surgery 18 18 happens in almost 10 percent of our patients, so it's a certain -- are very immunosuppressive, so if --19 19 a huge -- a huge, huge medical problem. There's a very large body of evidence that 20 20 Q. And -- and I'm -- I'm -patients who receive blood transfusions have more 21 21 post-operative infections, more sepsis, more cardiac I apologize for completely misunderstanding 22 and pulmonary complications, so avoiding blood 22 the purpose of the study. Is -- I --23 transfusions is actually one of our main -- main 23 Is there some chemical that is evidence of 24 goals -- not avoiding, but limiting the number of 24 a -- a relatively mild cardiac damage --25 transfusions is one of the main goals here at the 25 A. Yeah.

•	Page 205	,	Page 207
1	Q that that you can look for that	1	A. Yes.
2	somebody might be walking around and having no idea	2	Q. Okay. And that
3	that they've had this mild mardi myocardial damage,	3	Are you in effect trying to replicate that
4	but it has but it manifests itself in a measurable	4	aspect of the Frank study with a a larger
5	way with this particular chemical?	5	population and and
6	A. We look at what's called troponin T, so	6	A. Yeah.
7	that's a cardiac enzyme that's ex well it's	7	O more
8	excreted by muscle cells when they die, and it's a	8	A. The Frank study did not measure troponin,
9	very, very sensitive marker, and they're a very strong	9	which is a strong weakness of the study. But of
10	predictor of post-operative mortality.	1.0	course, then, 20 years ago, troponin wasn't as
11	Q. Are and is	11	available and as established as they are nowadays.
12	Are you going to be looking at troponin T?	1.2	Q. Twenty years from now maybe there will be
13	A. Yes.	13	something else to
14	Q. Is that is that the primary outcome?	14	A. I hope so.
15	A. Yes.	15	Q. A more sensitive measure.
16	Q. Is it	16	A. Yeah.
17	So is the level of troponin T that you're	17	Q. Okay. If I could now direct your attention
	you're looking for such that it would demonstrate that	18	to Exhibit 244, the the Brandt et al paper on
18	somebody's already had enough cardiac injury that	19	comparing the resistive polymer to forced-air warming,
19		20	want and if you want to turn to page 37, I want to
20	they they ought to know about it?	1	· · · · · · · · · · · · · · · · · · ·
21 .	A. It would, yes. So the higher the level, the	21	read you part of the discussion that we plaintiffs'
22	more likely that the patient has strong symptoms. The	22	counsel asked you about. He didn't read this, so
23	problem with with surgery or the post-surgery	23	I'm my turn to to read it, a portion of it.
24	period is just that patients don't get the typical	24	MR. ASSAAD: Object to the preamble.
25	myocardial-injury chest pain, and so most of of	25	Q. "First, the blanket is stiffer and tends to
	Page 206		Page 208
1	of the myocardial injury is silent. Nevertheless,	1	wrinkle, which may reduce the surface area in contact
2	about I think one in 10 patients who have an elevated	2	with the patient's skin, thus reducing its
3	troponin level after surgery will be dead 30 days	3	effectiveness. Because there is no stream of warm
4	after surgery, which is it is significant.	4	air, the efficacy of the system, similar to all
5	Q. And and and I'm I'm clearly not	5	resistive-warming systems, is dependent on close skin
6	asking very clear questions and I apologize. But	1	
7		6	contact, and the blanket has to be placed on the
	are is are any of the strike that.	6 7	contact, and the blanket has to be placed on the patient correctly. Incorrect placement may explain
8	are is are any of the strike that. At the levels of troponin that you're going	1	patient correctly. Incorrect placement may explain
8 9	At the levels of troponin that you're going	7	patient correctly. Incorrect placement may explain the observed tendency of the rewarming curve in the FA
_	At the levels of troponin that you're going to be looking at as the primary outcome, do you	7 8	patient correctly. Incorrect placement may explain
9	At the levels of troponin that you're going to be looking at as the primary outcome, do you will you include as an adverse outcome from surgery	7 8 9	patient correctly. Incorrect placement may explain the observed tendency of the rewarming curve in the FA group to be steeper and the final mean core temperature in the RP group to be lower. Therefore,
9 10 11	At the levels of troponin that you're going to be looking at as the primary outcome, do you will you include as an adverse outcome from surgery troponin levels that are actually subclinical, that	7 8 9 10	patient correctly. Incorrect placement may explain the observed tendency of the rewarming curve in the FA group to be steeper and the final mean core temperature in the RP group to be lower. Therefore, the results of our study should be extrapolated with
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9 10 11 12 13	At the levels of troponin that you're going to be looking at as the primary outcome, do you will you include as an adverse outcome from surgery troponin levels that are actually subclinical, that that have not manifested themselves MR. ASSAAD: Object to form.	7 8 9 10 11 12 13	patient correctly. Incorrect placement may explain the observed tendency of the rewarming curve in the FA group to be steeper and the final mean core temperature in the RP group to be lower. Therefore, the results of our study should be extrapolated with care to settings in which the risk of severe intraoperative hypothermia is high, or those in which
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Page 209 Page 211 1 resistive-polymer blanket. In this case it was the 1 because the cleaning process is very often tedious and 2 Hot Dog; right? 2 equally expensive at least. 3 3 Q. You -- and --A. Yes. Q. And one of the things you're -- you're --4 And way earlier in your testimony this 5 you're cautioning about is that they -- they have to 5 morning I think you talked about the -- the switchover 6 be cleaned in between each surgical procedure, which 6 the -- from the use of the Bair Hugger to the -- the 7 takes manpower and cleaning equipment. And -- and --7 Stryker product, the Mistral unit --8 8 A. Yes. and that has to be done; otherwise, there can be a 9 risk of cross-contamination of pathogens from the one 9 Q. -- at the Cleveland Clinic, and I -- I --10 patient being directly placed on another -- on -- on 10 11 another patient; right? 1.1 You had said something about the comments of 12 12 your -- of the -- the nurse anesthetists and -- in --A. Yeah, absolutely. 13 Q. And going back up to the top where you talk 13 in using the Mistral blanket. What had --1.4 about the tendency of the blanket to wrinkle, are --1.4 What has been the feedback that you have 15 are you aware of any impact that that tendency of it 15 received from your staff about the -- the use -- about 16 to wrinkle has had on the -- on how effectively it can 16 the -- how the -- how the Mistral unit performs? 17 be cleaned in between surgical procedures? 17 A. I think people just had the feeling -- and 18 18 A. I --that's, of course, anecdotal so you must be careful --19 19 No, -that fewer patients have a core temperature greater 20 MR. ASSAAD: Objection. 20 than 6 -- 36 degrees when they drop them in the 21 A. -- I cannot -- I cannot comment on that. 21 recovery room as opposed to before. 22 22 Q. Have you -- have you heard any concerns Q. Now are those data that you collect? 23 about challenges to -- to cleaning the blankets in 23 A. These are data that we collect. 24 between procedures? 24 Q. And is -- so have -- are --2.5 25 A. I haven't, but then I -- I know very -- I Is there any discussion about doing some Page 210 Page 212 1 only --1 sort of a -- a --2 I don't know many institutions that use 2 A. I've already initiated this. It's a --3 3 these types of warming. We already are performing a data pull to 4 Q. And --4 look into this. 5 But a concern if you use one is that you --5 Q. So --6 you got to be sure to clean it thoroughly, including 6 And what will you be looking at in that data 7 7 all the wrinkles, all the folds, because if -set? 8 8 otherwise, you could be directly transferring A. We will look at --9 pathogens from one patient to another; right? 9 I think we started using Mistral-Air two 10 MR. ASSAAD: Objection to form. 10 years ago, in November or so, so what we will do is we 11 A. Yeah. 11 will choose two similar time periods, let's say 12 Q. Now you had --- I --- I ---12 February to -- February, March, April -- May, three 13 13 I believe you had said that when you wrote months two years ago or one and a half years or -- or 14 this, the cost -- you -- your understanding was the 14 one and a half years ago or whatever it -- even this 15 cost of the -- the Bair Hugger blanket was higher and 15 year, and compare core temperatures to a three-month the cost of the cleaning process for the resistive 16 16 period at the same time in a year -- in that year, the 17 17 blanket or the Hot Dog was -- was lower? And -same months, but only three years ago or four years 18 A. That I don't know. I -- I know that the --18 ago when we had the Bair Hugger. 19 that the forced-air blankets have come down 19 Q. So you would be comparing core temperatures 20 significantly in price. I -- I've -- I've never 20 at the com -- at time of completion of the surgery on 21 really looked. I mean that's -- that's the discussion 21 arrival at PACU? 22 part of a paper where you can make assumptions, but I 22 A. No. We -- we have all --23 haven't looked into the cleaning part. But I do know 23 We have core temperatures from after 24 that here at the Cleveland Clinic we more -- more --24 induction to anes -- of anesthesia to end of surgery 25 for many of our devices, actually moved to disposables 25 and at arrival in the PACU.

53 (Pages 209 to 212)

Page 213 Page 215 1 Q. So you can do the whole curve. 1 A. The bottom, "...the back of the patient..." 2 A. So we will do the entire time-weighted 2 Yeah. That just means that when you lie on the 3 average below a certain core temperature. 3 surface, the vessels on -- the perfusion on your back Q. Is that something you're doing just for 4 is a little bit compromised just all due to your own internal purposes, or do you -- would you expect to 5 weight because you are basically lying on -- on your 6 publish the results? 6 back, and if you apply heat to an area that has a 7 A. I probably would not publish. It's a 7 slightly decreased perfusion, it could cause burns quality-improvement project, and I mainly do that to 8 easier as opposed to if the perfusion would be 9 see whether I -- we want to stick to the Mistral-Air 9 completely okay. 10 or go back to Bair Hugger. 10 Q. So are -- are you familiar with the concept 11 Q. Do you have any plans, as part of the --11 of, in connection with -- with resistive blankets, of 12 this comparison of the Mistral to the --- to the Bair 12 thermal runaway? Does that have any meaning to you? 13 Hugger, to look at any other endpoints besides core 13 A. That term does not. 14 temperature? 14 Q. Your face told me it doesn't. 15 A. No. No. Because it's -- it's probably --15 A. No. 16 Three months isn't a long-enough time period 16 Q. Are you familiar with how the blanket 17 17 to have enough patients to look at other outcomes. regulates the amount of wattage that is sent to it? 18 It's not a bad idea, but we probably will --18 A. It depends on which kinds. Are we talking 19 And I think it's also different times. So 19 about water blankets or resistive heating? 20 20 if you look at data, whatever, in two thou -- 2012 and Q. Resistive, resistive blankets. 21 2016, many things have changed in between. It will be 21 A. I think I kind of know. 22 Q. I think --22 a very unfair comparison to look at outcomes such as 23 infections or myocardial outcomes because surgical 23 Are you familiar with the concept of a -- of 24 technique might have changed over time, other things 24 a -- of a sensor on the -- the resistive blankets 25 in the OR might have changed, anesthesia management 25 that -- that basically tells the unit how much power Page 214 Page 216 1 might have changed, so no, we will not look at 1 to keep sending into the blanket? 2 outcomes. 2 A. Yes. 3 3 Q. So the driver of this --Q. Okay. And are -- are you familiar with --4 A. Is temperature. 4 with burns that have resulted from those sensors 5 5 Q. -- particular quality-improvement project is becoming covered up or un -- folded under? 6 6 the concern that -- the anecdotal concern that core A. I have not used these devices since I was in 7 7 temperatures are lower -- have been lower with the Switzerland. We did a, years ago, a volunteer study 8 8 Mistral unit. in St. Louis which was a study where these devices --9 9 A. Exactly. where we had the first versions of these devices and 10 10 Q. Okay. I -- I'm sorry, I -we did get burns. Since then I think they have 11 If we could go back to Exhibit 244, one 11 improved quite a bit so I've not really heard much 12 other thing I want to ask you about: on page 837 you 12 about burn or even pressure necrosis with those. 13 13 said, "...posterior patient-warming systems do -- do Q. Have you ever recommended to the Cleveland 14 have the inherent disadvantage that warming the back 14 Clinic that it look into the possibility of switching 15 of the patient in the supine position is suboptimal 15 over to resistive blankets? 16 because of low perfusion in this area and the danger 16 A. No. 17 of pressure-heat injuries." 17 Q. Why? 18 Could you explain what you meant by 18 A. You know what? Not -- I always --19 19 "pressure-heat injuries." Honestly, no good reason. I think the 20 MR. ASSAAD: Where are you reading? Sorry. 20 newer -- there are very new blankets that even have 21 MR. GORDON: Page 837 of -- this is Exhibit 21 pressure-relief systems in them, and those -- those 22 244. 22 might actually work fairly well. They're probably 23 MR. ASSAAD: Yeah, but where I mean. 23 expensive. We've advised --24 MR. GORDON: It's almost to the bottom of 24 I've advised the clinic to switch to or to 25 25 the second column. use water-based garments only because they're very

54 (Pages 213 to 216)

	Page 217		Page 219
1	hard to use and they they not necessarily transfer	1	course you use a drill, then it starts splashing all
2	enough heat. Otherwise, I don't know too much about	2	over the place.
3	resistive. This I think maybe this was, I think,	3	Q. And the
4	the only study I really did with these devices.	4	Is there something to suck out the water?
5	Q. Do you have any safety concerns about	5	A. Yes, there is.
6	forced-air warming?	6	Q. And and all of that's happening right at
7	A. No.	7	the surgical site.
8	Q. Way earlier, according to my notes, we	8	A. Yes.
9	did you were you were asked some questions about	9	Q. Again, earlier you were asked about the
10	things in the operating room that blow air directly	10	you know, the the you you would never you
11	onto patients.	11	would never want to introduce something that would
12	A. Yes.	12	cause harm; right?
13	Q. Do you remember that line of questions?	13	A. Correct.
14	Does the the Bair Hugger blanket blow air	14	Q. Everything, pretty much, in medicine has the
15	directly onto the surgical site?	15	potential to cause some harm; right?
16	A. The way how we put it on, I don't believe,	16	A. Correct.
17	because we actually we put our Bair Huggers on	17	MR. ASSAAD: Objection, lack of foundation,
18	one after the patient is draped. And so let's say,	18	assumes facts not in evidence.
. 19	for example, you have an upper-body cover, you have it	19	Q. For example, general anesthesia, there
20	taped right here across the patient's chest, and then	20	are there are potential complications and potential
21	you have all the OR drapes above it which themselves	21	bad outcomes for for some people from getting
22	are are are glued more or less to I	22	general anesthesia; right?
23	don't know the right term any more to the skin. So	23	A. Rarely nowadays, but yes.
24	I'm I'm not much worried about air blowing, getting	24	Q. Rarely. But for the
25	out in that direction.	25	In those rare events, that that's harm;
	Page 218		Page 220
1		1	
2	Q. And in an arthroplasty, hip or knee, A. Uh-huh	1 2	right?
~			
3		2	A. Absolutely.
3	Q do have you observed surgeons,	3	Q. And because of those that rare occasion
. 4	Q do have you observed surgeons, orthopedic surgeons using drills or saws?	3 4	Q. And because of those that rare occasion where somebody might be harmed, would that in your
. 4 5	Q do have you observed surgeons,orthopedic surgeons using drills or saws?A. Yeah.	3 4 5	Q. And because of those that rare occasion where somebody might be harmed, would that in your mind justify the i the deciding, well, we're
. 4 5 6	 Q do have you observed surgeons, orthopedic surgeons using drills or saws? A. Yeah. Q. Are the drills or saws used directly at the 	3 4 5 6	Q. And because of those that rare occasion where somebody might be harmed, would that in your mind justify the i the deciding, well, we're never going to use general anesthesia?
4 5 6 7	 Q do have you observed surgeons, orthopedic surgeons using drills or saws? A. Yeah. Q. Are the drills or saws used directly at the surgical site? 	3 4 5 6 7	Q. And because of those that rare occasion where somebody might be harmed, would that in your mind justify the i the deciding, well, we're never going to use general anesthesia? A. No.
4 5 6 7 8	 Q do have you observed surgeons, orthopedic surgeons using drills or saws? A. Yeah. Q. Are the drills or saws used directly at the surgical site? A. Of course, yeah. 	3 4 5 6 7 8	 Q. And because of those that rare occasion where somebody might be harmed, would that in your mind justify the i the deciding, well, we're never going to use general anesthesia? A. No. Q. In fact, all of medicine involves a
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q do have you observed surgeons, orthopedic surgeons using drills or saws? A. Yeah. Q. Are the drills or saws used directly at the surgical site? A. Of course, yeah. Q. Do you know if those if the drills or saws have any kind of internal fan, cooling fan? MR. ASSAAD: Objection, lack of foundation. A. I don't. I don't. Q. When you when you've seen them used, do they generate any type of movement or activity or, you know, physical mechanical activity in the in the immediate A. They're all really loud, so I assume, yes. But the physical activity they generate, I don't know; I mean you see water spraying all over the place, but that's the only thing we see. Q. Do you see A. Yeah. Because they use they use	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And because of those that rare occasion where somebody might be harmed, would that in your mind justify the i the deciding, well, we're never going to use general anesthesia? A. No. Q. In fact, all of medicine involves a balancing of of risks A. Yeah. Q and benefits. A. Every drug, every device does. Q. In your resume you list a book chapter, I think it's your your the very first book chapter you list on page 43, that's Exhibit 237, and the title is "Does intraoperative core hypothermia increase the incidence of surgical wound infections and prolong hospitalization?" And the the date is 1994; is that right? A. I still haven't found it yet. Q. Number one. A. Oh, number one. Okay.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q do have you observed surgeons, orthopedic surgeons using drills or saws? A. Yeah. Q. Are the drills or saws used directly at the surgical site? A. Of course, yeah. Q. Do you know if those if the drills or saws have any kind of internal fan, cooling fan? MR. ASSAAD: Objection, lack of foundation. A. I don't. I don't. Q. When you when you've seen them used, do they generate any type of movement or activity or, you know, physical mechanical activity in the in the immediate A. They're all really loud, so I assume, yes. But the physical activity they generate, I don't know; I mean you see water spraying all over the place, but that's the only thing we see. Q. Do you see A. Yeah. Because they use they use How do you call these things, the opposite	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. And because of those that rare occasion where somebody might be harmed, would that in your mind justify the i the deciding, well, we're never going to use general anesthesia? A. No. Q. In fact, all of medicine involves a balancing of of risks A. Yeah. Q and benefits. A. Every drug, every device does. Q. In your resume you list a book chapter, I think it's your your the very first book chapter you list on page 43, that's Exhibit 237, and the title is "Does intraoperative core hypothermia increase the incidence of surgical wound infections and prolong hospitalization?" And the the date is 1994; is that right? A. I still haven't found it yet. Q. Number one. A. Oh, number one. Okay. Q. The very first one.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q do have you observed surgeons, orthopedic surgeons using drills or saws? A. Yeah. Q. Are the drills or saws used directly at the surgical site? A. Of course, yeah. Q. Do you know if those if the drills or saws have any kind of internal fan, cooling fan? MR. ASSAAD: Objection, lack of foundation. A. I don't. I don't. Q. When you when you've seen them used, do they generate any type of movement or activity or, you know, physical mechanical activity in the in the immediate A. They're all really loud, so I assume, yes. But the physical activity they generate, I don't know; I mean you see water spraying all over the place, but that's the only thing we see. Q. Do you see A. Yeah. Because they use they use	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And because of those that rare occasion where somebody might be harmed, would that in your mind justify the i the deciding, well, we're never going to use general anesthesia? A. No. Q. In fact, all of medicine involves a balancing of of risks A. Yeah. Q and benefits. A. Every drug, every device does. Q. In your resume you list a book chapter, I think it's your your the very first book chapter you list on page 43, that's Exhibit 237, and the title is "Does intraoperative core hypothermia increase the incidence of surgical wound infections and prolong hospitalization?" And the the date is 1994; is that right? A. I still haven't found it yet. Q. Number one. A. Oh, number one. Okay.

55 (Pages 217 to 220)

Page 221 Page 223 Were -- there was -- you -- some earlier questions 1 are less than an hour. But then, of course, very few 2 about your 1996 study being the first randomized 2 procedures here are less than an hour. I am -- I'm --3 I'm only little bit hesitant, and I was 3 controlled trial that -- that demonstrated that the main -- maintenance of normothermia reduced 4 before as well, only because the whole thing -- the 5 5 whole discussion about prewarming and redistribution infections. In 1994, when you wrote this chapter, did 6 6 you have -- did you offer any answers to that -- to hypothermia has changed a little bit over the past few 7 years, so what we thought 10 years ago might not be so that first question, does intraoperative core 8 8 hypothermia increase the incidence of surgical wound true any more. And redistribution isn't as much as it 9 infections? 9 used to be. So it's an area that still has to be 10 A. I probably had no clue then. No. I -- I 10 researched quite a bit in my mind, and that's why I'm 11 don't -- I don't know. This is such an old chapter --11 hesitant when these questions come. But I think at 12 Q. I -- I -- I -- I -- I understand, and 12 this given point in time I would -- most surgeries 13 13 that are less than an hour, I wouldn't do much in my -- my -- my -- my question, though, is do you 14 regards to active warming. 14 recall back in 1994 when you wrote this chapter that 15 15 Q. What -- what do you mean the "redistribution there was some -- there were --16 isn't as much as it used to be?" 16 A. Huh-uh. 17 17 Q. -- there was some reason for you and your --A. When we did our first studies about 15, 20 18 years ago, we actually published that anesthesia 18 your co-authors of this chapter to be concerned about 19 causes a 1- to 1.5-degree redistribution hypothermia, 19 the issue as -- of -- of whether intraoperative core 20 hypothermia could increase the incidence of surgical 20 and this is not what we see nowadays in our data. So wound infections? 21 21 studies in the last six, seven years actually only 22 22 A. Yeah, because -show .5, .7, maximum .8 degrees of redistribution 23 MR. ASSAAD: Object to the form, object to 23 hypothermia. 2.4 the preamble, lack of foundation, assumes facts not in 24 Q. What -- what are the reasons for that? 25 25 A. I think that patients come to surgery maybe evidence. Page 222 Page 224 1 A. I mean in '94 we were about to start our --1. in better conditions nowadays as opposed to 20 years 2 2 or we were in the middle, actually, of our large -ago. So 20 years ago patients didn't come from home, 3 3 not "large" -- of our 200-patient study. I -- I they usually for any type of surgery will be in the 4 assume what we did here is look at basic science 4 hospital a few days before surgery, so they would 5 5 indications, so how hypothermia affects immune already be hypervolemic and probably uncomfortable 6 function and other things. But that's all I can think 6 and, and, and, so -- and all -- all these things, 7 7 of. There was no other evidence at that time. of course, affect how induction of anesthesia pans 8 8 Q. Earlier you -- you were asked about patients out. And now when patients come from home, they 9 that -- that -- surgeries -- surgical procedures where 9 probably have a very good overall body-heat content 10 you -- you don't think warming is necessary. You 10 already, they aren't hyp -- they shouldn't be 11 mentioned eyes. Then you were asked about procedures 11 hypothermic because they're awake. So it's not 12 under an hour, and I -- I don't want to put words in 12 totally clear to us yet why that has changed so much, 13 13 your mouth, but what -- what was your -- what was your but it's clear that it has changed. It's -- it's --14 answer to whether procedures under an hour should have 14 it's obvious in many publications. 15 15 Q. You remain an advocate of active warming. active warming or not? 16 16 MR. ASSAAD: Objection to form. Objection A. I think I said it's not absolutely necessary 17 because what you get in the first hour is 17 to form. 18 18 Q. Is that correct? redistribution hypothermia, and you get that due to 19 induction of anesthesia and you almost get that no .19 A. Yes, I do. I am because --20 matter whether you warm or don't. 20 I mean we always talk about evidence-based 21 Q. Are there circumstances where you would 21 medicine, but we have so little evidence in any type 22 nevertheless recommend -- recommend active warming for 22 of field. I mean we all try to get as much as we do, 23 23 procedures of less than an hour? and that's why we are now doing this -- this large 24 24 A. I have to tell you that here at the Protect study, because we want to get the evidence.

56 (Pages 221 to 224)

But I also believe that a little bit still in -- in

Cleveland Clinic we warm everybody, even the ones that

2.5

25

	Page 225		Page 227
1	medicine is art and the way you you understand the	1	Q. Why not?
2	existing data. So yes, I I do still believe in	2	A. I will not be able
3	these things.	3	You will not be able to publish that
4	Q. And are are you including the clinical	4	anywhere in the western world.
5	judgment applied to	5	Q. Why not?
6	A. Yes, absolutely.	6	A. Even if you
7	Q existing data where maybe you can't	7	That's just how that's just how it works.
8	connect all the dots empirically but	8	I don't know why. Even though you're right, it might
9	A. Yes.	9	not be standard of care, but even that I think is
10	Q your clinical judgment comes into play?	10	considered unethical, that you just go to a country
11	A. Yeah. And you can also only interpret data	11	that is underserved and
12	in the context of the time, so what might have been	1.2	Q. Does fluid warming, is it as effective as
13	very true 20 years ago might not be now, and vice	13	forced-air warming?
14	versa, and conditions change, types of surgery change,	14	A. No.
15	patients change, we change. So I think every	15	MR. GORDON: Object to the form of the
16	physician needs to put together look at the data	16	question.
17	as as as a whole and interpret it for	1.7	MR. ASSAAD: Basis. Basis.
18	themselves.	18	MR. GORDON: In in all contexts? In
19	MR. GORDON: Okay. Thank you. I'm done.	19	what
20	THE WITNESS: You're welcome.	20	MR. ASSAAD: I'm asking in general. That's
21	MR. ASSAAD: I have a few follow-up	21	not a basis.
. 22	questions.	22	Go ahead and answer.
23	THE WITNESS: Yeah.	23	A. I can answer that anyway. I believe it is
24 25	(Discussion off the stenographic record.) BY MR. ASSAAD:	24	not because greatest part of fluid warming is not
25	BI W.R. ASSAAD;	25	considered active warming. So if you give only little
	Page 226		Page 228
1	Q. You say to do the the the 1996 test	1	bit of fluid and warm it to you can only warm
2	today would be unethical.	2	fluids to 37 degrees because that's our safely
3	A. Yes.	3	our that's our body temperature. If you only give
4	Q. Okay. And that's why you're going to China	4	a little bit of fluid and it's only half a degree
5	to do the studies, because they don't have forced-air	5	warmer than your core temperature, then you cannot
6	warming as a standard of care; correct?	6	transfer any heat with it. If you give eight liters
. 7	A. No. Absolutely not. The the study	7	in an hour, then of course you can transfer
8	even the stud	. 8	transfer heat even with fluids. But in the general
9	First of all, the study will happen here at	9	setting it's not considered active warming. And we
10	the Cleveland Clinic as well, and the main reason of	10	only do it here for very large cases like trauma or
11	the study is to look at a much lesser degree of	11	liver transplants, so
12	hypothermia. So while in '96 patients were normally,	12	Q. And and you guys had you had a
13	as you said before, going down to 34.5 degrees, the	13	discussion with counsel regarding hypothermia causes
14	limit for the current study is 35.5. So absolutely	14	an increase in transfusions; correct?
15	not.	.15	A. Causes. Yes.
16 17	Q. There are areas in the world where forced-	16	Q. Okay. And and increased transfusions
17 18	air warming or warming patients is not the standard of	17	could possibly cause an increase in infection rates.
18 19	care. A. Correct.	18	A. Could be associated, yes.
20	Okay. So if you really want to redo the	19	Q. Associated.
21	study, you could go to one of those countries and	20 21	A. I don't want to say "cause."Q. Okay. And if you are at 35 degrees for two
22	and and	22	hours, you agree with me based on the 2015 study that
-,-	A. Huh-uh.	23	there's no increase of blood transfusions.
23	120 ALUICUII.	23	meres no increase or proof fransitusions.
23 24	O do the study there	24	A No
23 24 25	Q do the study there.A. No, I cannot.	24 25	A. No.Q. What would be the increase?

	Page 229	1	Page 231
1	A. I don't know, and I'm not sure that I can	1	reliability and that previous studies were done with
2	calculate it here. But if you are at 35 degrees for	2	much larger temperature differences than are currently
3	two hours, you should be at considerable risk for	. 3	allowed."
4	blood loss.	4	I want to focus on the next paragraph.
,5	Q. What about for one hour?	5	"Others have noticed the same thing. See,
6	A. Probably less.	6	for example, page 13 of the current issue of the ASA
7	Q. Isn't it isn't it a 1.0 odds ratio? If	7	newsletter which includes the following: 'The
8	you look at your paper, two degrees for one hour gives	8	normothermia measure has the weakest evidence
9	an odds ratio of 1.0; correct?	9	supporting its ability to improve outcomes and is a
10	A. Where is the paper? I can't remember.	10	complex, non-intuitive measure involving multiple
11	MS. DIFRANCO: What's the exhibit number?	11	inclusion and exclusion criteria.' And in a different
12	MR. ASSAAD: Exhibit 243.	12	article on page 16: 'outcome measures such as
13	A. I'm slowly zoning out here, that's why I'm	13	mortality and readmission have moved to center
14	not concentrating.	14	
15	_	15	stage, and process measures, such as antibiotic
16	I don't know what we used as odds ratio as as reference,	16	timing, are less and less seen as acceptable new
17			measures of quality."
	Q. You used 36 degrees at one hour.	17.	Did I read that correctly?
18	A. Yeah. I I	18	A. Yeah.
19	You know, honestly, I think I would have to	19	Q. So are you telling me today that your
20	go over that with our statistician.	20	testimony is you're not aware of other people I
21	Q. Well isn't an odds ratio the increased risk	21	mean I strike that.
22	of something occurring?	22 -	I assume you read the ASA newsletter;
23	A. It is. But I can't see what one or I	23	correct?
24	At least at this point in time any more I	24	A. Very rarely.
25	don't understand exactly what the one was. The	25	Q. Okay. Did you have any discussions with Dr.
	Page 230		Page 232
1	•	1	-
1 2	area	1	Sessler regarding this e-mail with respect to, "Hey,
3	It's not one degree. The area under 37	2 3	what are you talking about? Other people have issues
l .	degrees times hour.		with normothermia and its weak evidence?"
4	Q. If you don't understand the study, that's	4	A. I don't recall it, but I probably have.
5	fine. We can we can move on.	5	Q. Okay. So it shouldn't be something new
6	A. Yes, let's move on.	6	today when I asked you the question that other people
7	(Exhibit 247 was marked for	7	have issues with normothermia and its effect on
8	identification.)	8	outcomes.
9	BY MR. ASSAAD:	9	MR. GORDON: Object to the form of the
10	Q. What's been marked as Exhibit No. 247 is an	10	question.
11	e-mail chain, and I want you to turn to the second	11 .	A. They are. It could be quite new because I'm
12	page where there's an e-mail from Dr. Sessler to	12	not remembering every e-mail from 2012.
13	numerous people at 3M, and you're copied on it as	13	Q. But you'd heard something about it back in
14	44 4 4		0010 17 1
l	well, on November 20th, 2012.	14	2012. You you got copied on this e-mail; correct?
15	THE WITNESS: That's this one?	15	A. Yes.
15 16	THE WITNESS: That's this one? MS. DIFRANCO: This one, yes. Yes.	15 16	A. Yes. Q. And do you read e-mails you receive from Dr.
15 16 17	THE WITNESS: That's this one? MS. DIFRANCO: This one, yes. Yes. A. Yeah.	15 16 17	A. Yes.Q. And do you read e-mails you receive from Dr.Sessler?
15 16	THE WITNESS: That's this one? MS. DIFRANCO: This one, yes. Yes. A. Yeah. Q. Do you recall receiving this e-mail?	15 16	A. Yes. Q. And do you read e-mails you receive from Dr.
15 16 17	THE WITNESS: That's this one? MS. DIFRANCO: This one, yes. Yes. A. Yeah. Q. Do you recall receiving this e-mail? A. I don't, but I'm on there.	15 16 17	A. Yes.Q. And do you read e-mails you receive from Dr.Sessler?
15 16 17 18	THE WITNESS: That's this one? MS. DIFRANCO: This one, yes. Yes. A. Yeah. Q. Do you recall receiving this e-mail?	15 16 17 18	A. Yes.Q. And do you read e-mails you receive from Dr.Sessler?A. Mostly.
15 16 17 18 19	THE WITNESS: That's this one? MS. DIFRANCO: This one, yes. Yes. A. Yeah. Q. Do you recall receiving this e-mail? A. I don't, but I'm on there.	15 16 17 18 19	 A. Yes. Q. And do you read e-mails you receive from Dr. Sessler? A. Mostly. Q. Now you said that Cleveland Clinic is is
15 16 17 18 19 20	THE WITNESS: That's this one? MS. DIFRANCO: This one, yes. Yes. A. Yeah. Q. Do you recall receiving this e-mail? A. I don't, but I'm on there. Q. Okay. It says from Daniel Sessler. It	15 16 17 18 19 20	 A. Yes. Q. And do you read e-mails you receive from Dr. Sessler? A. Mostly. Q. Now you said that Cleveland Clinic is is moving towards more disposables; correct?
15 16 17 18 19 20 21	THE WITNESS: That's this one? MS. DIFRANCO: This one, yes. Yes. A. Yeah. Q. Do you recall receiving this e-mail? A. I don't, but I'm on there. Q. Okay. It says from Daniel Sessler. It says, "Hi Folks,	15 16 17 18 19 20 21	 A. Yes. Q. And do you read e-mails you receive from Dr. Sessler? A. Mostly. Q. Now you said that Cleveland Clinic is is moving towards more disposables; correct? A. Yes.
15 16 17 18 19 20 21 22	THE WITNESS: That's this one? MS. DIFRANCO: This one, yes. Yes. A. Yeah. Q. Do you recall receiving this e-mail? A. I don't, but I'm on there. Q. Okay. It says from Daniel Sessler. It says, "Hi Folks, "One of the points Andrea and I tried to	15 16 17 18 19 20 21 22	 A. Yes. Q. And do you read e-mails you receive from Dr. Sessler? A. Mostly. Q. Now you said that Cleveland Clinic is is moving towards more disposables; correct? A. Yes. Q. They could
15 16 17 18 19 20 21 22 23	THE WITNESS: That's this one? MS. DIFRANCO: This one, yes. Yes. A. Yeah. Q. Do you recall receiving this e-mail? A. I don't, but I'm on there. Q. Okay. It says from Daniel Sessler. It says, "Hi Folks, "One of the points Andrea and I tried to make at the KOL meeting in Washington is that the	15 16 17 18 19 20 21 22 23	 A. Yes. Q. And do you read e-mails you receive from Dr. Sessler? A. Mostly. Q. Now you said that Cleveland Clinic is is moving towards more disposables; correct? A. Yes. Q. They could They charge the patient for those

58 (Pages 229 to 232)

	Page 233		Page 235
1	Q. Okay. So they, for example, buy the blanket	1	CERTIFICATE
2	from either Stryker or Bair Hugger for whatever the	2	I, Richard G. Stirewalt, hereby certify that
3	cost is, and they mark it up and and charge it to	3	I am qualified as a verbatim shorthand reporter, that
4	the patient.	4	I took in stenographic shorthand the deposition of DR.
5 -	A. I don't know whether we directly charge	5	ANDREA KURZ at the time and place aforesaid, and that
6	every single one of that items or whether it's part	6	the foregoing transcript is a true and correct, full
7	a part of an anesthesia package type of thing. So I	7	and complete transcription of said shorthand notes, to
8	don't I don't think that, if you look at your	8	the best of my ability.
9	invoice from the Cleveland Clinic, that you see	9	Dated at Deerwood, Minnesota, this 19th day
10	everything, the IV and everything in there.	10	of January, 2017.
11	Q. Well you do see Bair Hugger blankets.	11	or building, 2017.
12	A. I don't know.	12	•
13	Q. Okay.	13	
14	A. I don't know.	14	•
15	Q. Do you know the number of patients that	15	
16	or number of total hip or total or total knee	16	•
17	arthroplasty patients that result in some sort of	17	RICHARD G. STIREWALT
18	cardiac injury after surgery?	18	Registered Professional Reporter
19	A. I can make a very good assumption, which is	19	Notary Public
20	10 percent.	20	1 total f tubile
21	Q. Ten percent have a cardiac injury.	21	
22	A. Ten per	.22	
23	Eight to 10 percent will probably, and	23	
24	especially after the big joints, yes.	24	
25	Q. And if those patients are warmed, what's the	25	
	Page 234	-	
. 1	reduction in cardiac injury?		
2	A. I don't know.		
. 3	Q. Okay. You don't		
4	If any. You don't know. There might be no		
5	reduction; correct?		
6	A. There		
7	From what I know, I assume there is some,		
8	but I don't know. That's why we do the study.		•
9	Q. Are you currently aware that 3M has acquired		•
10	the exclusive right to a conductive blanket?		
11	A. I'm not.		
12	Q. No discussions with 3M?		
13	A. No.		
14	MR. ASSAAD: That's all I have.		
15	MR. GORDON: Thank you.	}	
16	MR. ASSAAD: Thank you.		
17	MS. DIFRANCO: All right. We'll waive the	1	S. Carlotte and Ca
18	witness's signature.		
19	THE REPORTER: Off the record, please.		
20	(Deposition concluded.)		
21			
22			
22			
22 23			

59 (Pages 233 to 235)